EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC. Defendants.	)	C.A. No. 22-252 (MSG) **JURY TRIAL DEMANDED** **HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL'S EYES ONLY - FILED UNDER SEAL**
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	)	

DEFENDANTS' COUNTERCLAIMS AND ANSWER TO AMENDED COMPLAINT
DECLARATORY JUDGMENT COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") demand a trial by jury on all issues so triable and assert the following counterclaims against Plaintiffs/Counterclaim-Defendants Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant"):

INTRODUCTION

1. Moderna brings these counterclaims in response to Arbutus and Genevant's lawsuit, which baselessly seeks to profit from Moderna's innovations that led to its ground-breaking mRNA-1273 "COVID-19 Vaccine." Specifically, Moderna asks this Court to declare that Moderna's COVID-19 Vaccine does not infringe the Asserted Patents, and that those patents are invalid. In short, this lawsuit will confirm that Moderna and its scientists, employees, and

collaborators are the true innovators in the mRNA delivery technology that led to its lifesaving COVID-19 Vaccine. Plaintiffs played no role in Moderna's significant accomplishments.

A. Moderna's Development of mRNA Medicines Using Lipid Nanoparticle Delivery

2. For a decade before COVID-19 emerged, Moderna had been pioneering a new class of medicines made of messenger RNA, or mRNA, and developed its own platform technologies that could deliver mRNA in a variety of therapeutic and prophylactic applications, including vaccines.[1] These mRNA medicines have the potential to treat and prevent a wide range of diseases—from infectious diseases like influenza and HIV, to autoimmune and cardiovascular diseases and rare forms of cancer. Over the past twelve years, Moderna has worked diligently in its laboratories to pioneer a number of fundamental breakthroughs in the field of mRNA technology. These discoveries span all aspects of mRNA medicines—from the characteristics and design of the mRNA itself and the protein it encodes, to the technologies to deliver mRNA to patients safely and effectively.

3. Included among the mRNA advancements that Moderna developed over years of extensive work, is its proprietary lipid nanoparticle ("LNP") delivery technologies to encapsulate the mRNA for delivery.[2] The LNPs function to protect the mRNA and deliver it into cells.[3]

4. Moderna invested years of work and resources to develop LNPs that are tailored to work with mRNA. Those efforts included developing novel proprietary lipids and optimal lipid

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[1] D.I. 17-1, Ex. B (Decl. of Shaun Ryan, Mot. to Supplement the Record to Provide Evidence of Standing) ¶ 2.

[2] *Id.* ¶¶ 2-3.

[3] *Id.*

compositions, and improving LNP manufacturing processes. Moderna's inventions in this area have been recognized with multiple U.S. patents.[4, 5]

5. Moderna's innovative proprietary LNP formulation technology, developed to address the complex problem of reliably delivering mRNA to a patient, goes well beyond the rudimentary, early technology for delivery of siRNA described in Arbutus's Asserted Patents, nor is it covered by those patents.

B. Arbutus's Failed Attempts to Develop Products of its Own

6. In contrast to Moderna's proprietary LNP technology to deliver mRNA, Arbutus (and its predecessor Protiva Biotherapeutics, Inc., "Protiva") conducted research relating to delivery of small interfering RNA ("siRNA"), small pieces of RNA "about 15–60 . . . nucleotides in length" as defined by Arbutus. *See, e.g.*, U.S. Patent No. 8,058,069 ("'069 Patent") at 6:55–66. siRNA is a far cry from the long, complex mRNA that Moderna's technology is designed to deliver. By way of example, Moderna's COVID-19 Vaccine delivers mRNA that is approximately 4,000 nucleotides—over 60 times the length contemplated by the Arbutus patents.

7. None of the Asserted Patents focus on mRNA. For example, the specification of the '069 Patent (and related Asserted Patents) focuses on siRNA, not mRNA, discussing "Selection of siRNA Sequences," "Generating siRNA Molecules," "Modifying siRNA Sequences," and "Target Genes" of siRNA. *See, e.g.*, '069 Patent at cols. 29, 32, 33, and 35. Indeed, all 11 examples of the '069 Patent (and its asserted family members) are directed to "nucleic acid-lipid particles" comprising siRNA—none involve mRNA. *Id*. at 67:64–86:18; *see also* U.S. Patent 9,504,651 at

[4] https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8.

[5] *E.g.*, https://www.modernatx.com/patents.

cols. 14–19 (Examples 1–8, none of which are directed to mRNA formulations). This is consistent with Arbutus predecessor Protiva's public statements at the time that the company was "focused on" "formulations for RNAi therapeutics."[6] As another example, the '651 Patent focuses on plasmid DNA, rather than mRNA. *See* '651 Patent at 2:17–19 ("The present invention can be used to form lipid vesicles that contain encapsulated plasmid DNA or small molecule drugs."), and cols. 14–15.

8. Tellingly, Plaintiffs/Counterclaim Defendants never developed an LNP capable of delivering mRNA, let alone manufactured or sold any approved products of their own, whether siRNA or mRNA-based.

9. Failing to develop any products of its own, Arbutus instead improperly expanded the scope of its patent estate in an attempt to cover the inventions of others, including pioneers like Moderna. Consequently, the purported inventions that Arbutus lays claim to in the Asserted Patents bear no resemblance to the rudimentary technology described in the specifications.

C. Moderna's Development and Sale of its COVID-19 Vaccine

10. The SARS-CoV2 virus, which causes COVID-19, was first detected in December 2019. On January 10, 2020, the genetic sequence of the SARS-CoV-2 virus became public.[7] Leveraging its decade of research and proprietary technologies, Moderna quickly responded when the pandemic struck, swiftly developing, manufacturing, and providing doses of its COVID-19 vaccine to people around the world. The COVID-19 Vaccine, also referred to as the mRNA-1273 vaccine, uses Moderna's proprietary LNP delivery technology that Moderna developed and

[6] https://investor.arbutusbio.com/news-releases/news-release-details/tekmira-pharmaceuticals-and-protiva-biotherapeutics-announce-0.

[7] "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness," bioRvix.org, at 5–6 (June 11, 2020) ("Moderna/NIH Preprint").

described years earlier.[8] For that groundbreaking work, Moderna's scientists were recently honored by the American Chemistry Society's 2022 Heroes of Chemistry Award, the highest honor for industrial chemical scientists, recognizing their "work developing formulations that protect against . . . COVID-19."[9]

11. Following the declaration of a public health emergency, Moderna entered into numerous agreements with the U.S. Government regarding its COVID-19 Vaccine. In April 2020, Moderna entered into a grant agreement with the Biomedical Advanced Research and Development Authority ("BARDA")—an office of HHS—to support clinical development of the mRNA-1273 vaccine.[10] BARDA chose to partner with Moderna to develop the COVID-19 vaccine because "Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus."[11]

12. Once Moderna had obtained promising clinical results, on August 9, 2020, ModernaTX, Inc. entered into a supply contract with the Army Contracting Command of the U.S. Department of Defense, Contract No. W911QY20C0100 ("C0100 Contract").[12] Under the C0100 Contract, Moderna was obligated to produce and deliver doses of its COVID-19 Vaccine to the U.S. Government, with the option to supply additional doses. The C0100 Contract specifically

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8 https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8.

9 https://pubs.acs.org/doi/10.1021/cen-10028-acsnews2.

10 https://www.hhs.gov/sites/default/files/moderna-75a50120c00034.pdf (BARDA Contract) at 9.

11 *Id.* at 9.

12 D.I. 17-1, Ex. A.

states that Moderna manufactured the COVID-19 Vaccine doses "for the United States Government."[13] The C0100 contract also incorporates by reference FAR 52.227-1, entitled "Authorization and Consent," and FAR 52.227-1 Alt I, entitled "Authorization And Consent (JUN 2020) - Alternate I."[14]

13. Moderna received unprecedented emergency use authorization for its COVID-19 Vaccine in the U.S. from the Food & Drug Administration ("FDA") on December 18, 2020—within less than a year of beginning development. Promptly thereafter, Moderna shipped U.S.-manufactured COVID-19 Vaccine doses to the U.S. Government pursuant to the C0100 Contract. Moderna also supplied foreign governments with doses of the COVID-19 Vaccine. On January 31, 2022, Moderna received full approval from the FDA for its Biologics License Application for the COVID-19 Vaccine.[15]

PARTIES

14. Moderna, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139.

15. ModernaTX, Inc. is a corporation organized and existing under the laws of Delaware with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139.

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13 *Id.* at 19.

14 *Id*. at 46.

15 Press Release (Jan. 31, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

16. Upon information and belief, Plaintiff/Counterclaim-Defendant Arbutus Biopharma Corporation is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974.

17. Upon information and belief, Plaintiff/Counterclaim-Defendant Genevant Sciences GmbH is a company organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland.

NATURE OF ACTION

18. Moderna seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., that U.S. Patent Nos. 8,058,069 (the "'069 Patent"), 8,492,359 (the "'359 Patent"), 8,822,668 (the "'668 Patent"), 9,364,435 (the "'435 Patent"), 9,504,651 (the "'651 Patent"), and 11,141,378 (the "'378 Patent") (collectively, "Asserted Patents") are invalid and/or not infringed.

JURISDICTION AND VENUE

19. This Court has exclusive subject matter jurisdiction over this action pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338; and the patent laws of the United States, 35 U.S.C. § 1 *et seq*.

20. This Court has personal jurisdiction over Arbutus and Genevant because each has subjected itself to the jurisdiction of this Court by filing the Amended Complaint.

21. Venue in this Court is proper based on the choice of forum by Plaintiffs and pursuant to 28 U.S.C. §§ 1391(b)-(c), and 1400(b).

FACTUAL BACKGROUND

22. On or about November 15, 2011, the '069 Patent was issued to Protiva Biotherapeutics, Inc.

23. On or about July 23, 2013, the '359 Patent was issued to Protiva Biotherapeutics, Inc.

24. On or about September 2, 2014, the '668 Patent was issued to Protiva Biotherapeutics, Inc.

25. On or about June 14, 2016, the '435 Patent was issued to Protiva Biotherapeutics, Inc.

26. On or about November 29, 2016, the '651 Patent was issued to Protiva Biotherapeutics, Inc.

27. On or about October 12, 2021, the '378 Patent was issued to Arbutus Biopharma Corporation.

28. Arbutus purports to be the owner and assignee of all Asserted Patents.

29. Genevant purports to be the exclusive licensee to all Asserted Patents.

30. On February 28, 2022, Plaintiffs Arbutus and Genevant filed a lawsuit against Moderna asserting that Moderna's COVID-19 Vaccine infringes the Asserted Patents.

31. Pursuant to 28 U.S.C. § 2201(a), an actual and justiciable controversy has arisen and exists between Moderna and Plaintiffs. Moderna is entitled to a judicial determination and declaration that it has not infringed and is not infringing the Asserted Patents, and that the Asserted Patents are invalid.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '069 PATENT

32. Moderna repeats and incorporates paragraphs 1-31 as if fully set forth herein.

33. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '069 Patent.

34. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '069 Patent.

35. Moderna has not infringed and is not infringing any valid claim of the '069 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '069 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '069 Patent depend from claim 1.

36. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '069 Patent, either literally or under the doctrine of equivalents.

COUNT II
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '359 PATENT

37. Moderna repeats and incorporates paragraphs 1-36 as if fully set forth herein.

38. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '359 Patent.

39. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '359 Patent.

40. Moderna has not infringed and is not infringing any valid claim of the '359 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '359 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '359 Patent depend from claim 1.

41. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '359 Patent, either literally or under the doctrine of equivalents.

COUNT III
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '668 PATENT

42. Moderna repeats and incorporates paragraphs 1-41 as if fully set forth herein.

43. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '668 Patent.

44. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '668 Patent.

45. Moderna has not infringed and is not infringing any valid claim of the '668 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '668 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '668 Patent depend from claim 1.

46. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '668 Patent, either literally or under the doctrine of equivalents.

COUNT IV
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '435 PATENT

47. Moderna repeats and incorporates paragraphs 1-46 as if fully set forth herein.

48. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '435 Patent.

49. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '435 Patent.

50. Moderna has not infringed and is not infringing any valid claim of the '435 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of at least claim 7 of the '435 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "cationic lipid") in the claimed ratios, and all dependent claims of the '435 Patent depend from claim 1.

51. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '435 Patent, either literally or under the doctrine of equivalents.

COUNT V
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '651 PATENT

52. Moderna repeats and incorporates paragraphs 1-51 as if fully set forth herein.

53. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '651 Patent.

54. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '651 Patent.

55. Moderna has not infringed and is not infringing any valid claim of the '651 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '651 Patent at least because it does not comprise the claimed "lipid vesicles . . . wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles," and all dependent claims of the '651 Patent depend from claim 1.

56. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '651 Patent, either literally or under the doctrine of equivalents.

COUNT VI
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '378 PATENT

57. Moderna repeats and incorporates paragraphs 1-56 as if fully set forth herein.

58. Plaintiffs have brought claims against Moderna alleging Moderna's COVID-19 Vaccine infringes the '378 Patent.

59. A real, immediate, and justiciable controversy exists between Plaintiffs and Moderna regarding Moderna's alleged infringement of the '378 Patent.

60. Moderna has not infringed and is not infringing any valid claim of the '378 Patent, willfully or otherwise, directly or indirectly, either literally or by application of the doctrine of equivalents. For example, Moderna's COVID-19 Vaccine does not meet each and every element of claim 1 of the '378 Patent at least because it does not comprise a nucleic acid-lipid particle comprising the claimed lipids (including, for example, the "polyethyleneglycol (PEG)-lipid conjugate") in the claimed ratios, and all dependent claims of the '378 Patent depend from claim 1.

61. Moderna is entitled to a declaratory judgment that Moderna does not infringe, either directly or indirectly, and has not infringed, either directly or indirectly, any valid claim of the '378 Patent, either literally or under the doctrine of equivalents.

COUNT VII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '069 PATENT

62. Moderna repeats and incorporates paragraphs 1-61 as if fully set forth herein.

63. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '069 Patent.

64. Moderna alleges that the claims of the '069 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '069 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

65. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

66. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, *inter alia*, the validity of the claims of the '069 Patent.

67. Moderna is entitled to a declaration that one or more claims of the '069 Patent are invalid.

COUNT VIII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '359 PATENT

68. Moderna repeats and incorporates paragraphs 1-67 as if fully set forth herein.

69. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '359 Patent.

70. Moderna alleges that the claims of the '359 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '359 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

71. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

72. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '359 Patent.

73. Moderna is entitled to a declaration that one or more claims of the '359 Patent are invalid.

COUNT IX
DECLARATORY JUDGMENT OF INVALIDITY OF THE '668 PATENT

74. Moderna repeats and incorporates paragraphs 1-73 as if fully set forth herein.

75. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '668 Patent.

76. Moderna alleges that the claims of the '668 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '668 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

77. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

78. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '668 Patent.

79. Moderna is entitled to a declaration that one or more claims of the '668 Patent are invalid.

COUNT X
DECLARATORY JUDGMENT OF INVALIDITY OF THE '435 PATENT

80. Moderna repeats and incorporates paragraphs 1-79 as if fully set forth herein.

81. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '435 Patent.

82. Moderna alleges that the claims of the '435 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, 7,807,815 and/or 9,814,777, and the claims of the '435 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

83. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "non-cationic lipid" and "conjugated lipid." As another example, claim 1 recites compositions comprising the broad genus of "nucleic acid[s]," but, other than siRNA, the specification fails to describe or enable any examples of nucleic acids including mRNA.

84. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '435 Patent.

85. Moderna is entitled to a declaration that one or more claims of the '435 Patent are invalid.

COUNT XI
DECLARATORY JUDGMENT OF INVALIDITY OF THE '651 PATENT

86. Moderna repeats and incorporates paragraphs 1-85 as if fully set forth herein.

87. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '651 Patent.

88. Moderna alleges that the claims of the '651 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112. For example, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 6,841,537 or U.S. 6,734,171, and the claims of the '651 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Further, claim 1 is anticipated or obvious in light of prior art references including, but not limited to, U.S. Patent No. 6,271,208, U.S. Patent No. 6,110,745, WO 01/11068 A2, WO 01/15726 A2, WO 98/51278, and Saravolac 2000.[16]

89. In addition, the specification fails to describe or enable, for example, the claimed "lipid vesicles" in claim 1 with the recited broad genus of "cationic lipid," "amphipathic lipid" and "polyethyleneglycol (PEG)-lipid," wherein "at least 70% of the mRNA in the formulation is fully encapsulated" as claimed. As another example, claim 1 recites compositions comprising "messenger RNA (mRNA)," but the specification fails to describe or enable any examples of "lipid vesicles" comprising mRNA, let alone those wherein "at least 70% of the mRNA in the formulation is fully encapsulated" as claimed.

90. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, *inter alia*, the validity of the claims of the '651 Patent.

91. Moderna is entitled to a declaration that one or more claims of the '651 Patent are invalid.

[16] Saravolac, E. G., et al. "Encapsulation of plasmid DNA in stabilized plasmid–lipid particles composed of different cationic lipid concentration for optimal transfection activity." *Journal of drug targeting* 7.6 (2000): 423-437.

COUNT XII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '378 PATENT

92. Moderna repeats and incorporates paragraphs 1-91 as if fully set forth herein.

93. Plaintiffs have brought claims against Moderna alleging infringement of at least claim 1 of the '378 Patent.

94. Moderna alleges that the claims of the '378 Patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or obviousness-type double patenting. For example, claim 1 is anticipated or obvious in light of prior art references including, but not limited to, Zimmerman 2006,[17] Thomas 2007,[18] and U.S. Patent Pub. No. 2008/0020058 A1. Further, there are no patentable distinctions between the earlier-expiring claims of U.S. Patent No. 9,006,191, and the claims of the '378 Patent, which are commonly owned and/or have common inventors, rendering them invalid under the doctrine of obviousness-type double patenting. Such obviousness-type double patenting references, alone or in combination with one or more prior art references such as U.S. Patent App. Pub. Nos. 2010/0015218, 2010/0297023, 2008/0249046, or U.S. Patent No. 7,005,140 also render the claims obvious.

95. In addition, the specification fails to describe or enable, for example, the claimed "nucleic acid-lipid particle[s]" in claim 1 with the recited ranges of "cationic lipid," "mixture of a phospholipid and cholesterol" and "polyethyleneglycol (PEG)-lipid conjugate." As another

[17] Zimmermann, Tracy S., et al. "RNAi-mediated gene silencing in non-human primates." *Nature* 441.7089 (2006): 111-114.

[18] Thomas, Mini, *et al.* "Non-viral siRNA delivery to the lung." *Advanced drug delivery reviews* 59.2-3 (2007): 124-133.

example, claim 1 recites compositions comprising the broad genus of "RNA," but, other than siRNA, the specification fails to describe or enable any examples of RNA including mRNA.

96. A present, genuine, and justiciable controversy exists between Moderna and Plaintiffs regarding, inter alia, the validity of the claims of the '378 Patent.

97. Moderna is entitled to a declaration that one or more claims of the '378 Patent are invalid.

ATTORNEYS' FEES

98. This is an exceptional case entitling Moderna to an award of their attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

99. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Moderna hereby respectfully requests a jury trial on all issues and claims so triable.

* * *

ANSWER

Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") hereby respond to Plaintiffs Arbutus Biopharma Corporation's ("Arbutus") and Genevant Sciences GmbH's ("Genevant") (collectively, "Plaintiffs") Amended Complaint as follows:

INTRODUCTION[1]

1. The impact of the COVID-19 pandemic, one of the greatest public health challenges in modem history, would be immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna's. Moderna brought its vaccine from lab bench to arms in record speed. That unprecedented accomplishment was made possible by Moderna's use of breakthrough technology Arbutus had already created and patented-a revolutionary lipid nanoparticle ("LNP") delivery platform that took the scientists of Arbutus years of painstaking work to develop and refine. Moderna was well aware of Arbutus's LNP patents and licensed them

[1] Moderna utilizes the headings from the Amended Complaint for convenience but does not admit or adopt the contents of the headings.

for other product programs, but it chose not to do so for its COVID-19 vaccine. Instead, it attempted to invalidate several of the patents before the United States Patent and Trademark Office, and when those efforts largely failed, Moderna simply used the patented technology without paying for it or even asking for a license. Plaintiffs do not seek an injunction or any relief in this case that would impede the sale or manufacture of Moderna's life-saving vaccine. They seek only fair compensation for the use of patented technology they developed with great effort and at great expense, without which Moderna's COVID-19 vaccine would not have been successful.

ANSWER: Moderna admits that to fight the COVID-19 pandemic, Moderna developed its COVID-19 Vaccine in record time through its own hard work and over a decade of experience developing mRNA vaccines. Moderna further admits that it had previously obtained a sub-license to the '069, '359, '668, '435, and '651 Patents or their predecessor applications (among other patents and applications), and had filed *inter partes* review petitions challenging the '069 and '435 Patents (as well as U.S. Patent No. 9,404,127 ("the '127 Patent"), which Plaintiffs do not assert in this case) before the United States Patent and Trademark Office. Moderna denies the remaining allegations in Paragraph 1.

2. Medicines using messenger ribonucleic acid (or "mRNA") technology, like Moderna's COVID-19 vaccine, rely on synthetic mRNA that enters the body's cells and instructs them to make proteins they would not necessarily make on their own. Moderna's COVID-19 vaccine, in particular, uses mRNA to cause cells to make a small piece of the virus that causes COVID-19 called the "spike protein." That small piece, which is harmless in isolation, prompts the body's immune system to produce antibodies that will recognize the spike protein if it is encountered in the future and destroy it. In this way, the vaccine equips a person's body ahead of time with antibodies to fight the COVID-19 virus if that person experiences a subsequent exposure.

ANSWER: Moderna admits the allegations in Paragraph 2.

3. Ever since the vast potential for mRNA-based vaccines and other mRNA-based medicines began to catch the attention of scientists more than two decades ago, the biggest technological hurdle to developing and deploying them has been devising a safe and effective way to deliver the mRNA to the cell. Without adequate protection, mRNA quickly degrades in the body. For mRNA vaccines like Moderna's to work, they must incorporate a mechanism for protecting the fragile mRNA, delivering it through cell membranes, and then releasing it inside the

cell. In the words of one Nobel Prize winning scientist, the secret for making RNA-based products work has always been "delivery, delivery, delivery."[2]

ANSWER: Moderna admits that its innovations in mRNA delivery contributed to the success of the COVID-19 Vaccine. Moderna states that Erika Check's article titled "RNA to the Rescue," published in 2003 and available at https://www.nature.com/articles/425010a, discusses disease therapies using siRNA, not mRNA, and quotes Philips Sharp's statement that "[t]he major hurdle right now is delivery, delivery, delivery." Moderna denies the remaining allegations in Paragraph 3.

4. Having vexed experts in the field for years, that problem eventually found a solution in the innovative research of Arbutus scientists. Their solution was ingenious: microscopic particles built from four carefully selected types of fat-like molecules, so small that they are measured in nanometers but still stable enough to shelter and protect an RNA molecule on a voyage through the human body to a target cell, and then through the target cell's membrane, before finally releasing the RNA. These tiny fat-like particles are called "lipid nanoparticles," or "LNPs." The United States Patent and Trademark Office has granted Arbutus several patents for its groundbreaking LNP technologies.

ANSWER: Moderna denies the allegations in Paragraph 4.

5. LNPs identified through Arbutus's pioneering work have been described as "crucial" to Moderna's COVID-19 vaccine, the first mRNA product the company was able to commercialize and the keystone of its financial success.[3] Without the LNPs Arbutus invented to safeguard the mRNA and deliver it into cells, the mRNA in Moderna's vaccine would degrade before ever reaching the cells it needs to enter and the vaccine would not work.

ANSWER: Moderna denies the allegations in Paragraph 5.

6. Moderna has long been aware of Arbutus's LNP intellectual property and its importance as a component of mRNA-based vaccines and other mRNA-based medicines. Several years before the pandemic, Moderna obtained licenses to use Arbutus's LNP patents for certain mRNA products directed to specific viral targets. But those licenses did not grant Moderna rights to use the technology for products targeting SARS-CoV-2, the virus that causes COVID-19 and

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[2] Erika Check, "RNA to the Rescue," *Nature* 425:10-12 (2003), *available at* https://www.nature.com/articles/425010a.

[3] Nathan Vardi, "Moderna's Mysterious Coronavirus Vaccine Delivery System," *Forbes.com,* July 29, 2020, *available at* https://www.forbes.com/sites/nathanvardi/2020/07/29/modernas-mysterious-coronavirus-vaccine-delivery-system/?sh=2995ba5f62d9.

that the vaccines at issue here target. Before it decided to use Arbutus's proven and patented technology as a crucial part of its COVID-19 vaccine, Moderna did not ask for a license to do so. Instead, it tried to convince the United States Patent and Trademark Office and, later, the United States Court of Appeals for the Federal Circuit to cancel several of Arbutus's LNP-related patents. But despite the failure of Moderna's attempts to eliminate Arbutus's patents, and despite Plaintiffs' efforts to resolve this dispute without litigation, Moderna has remained unwilling to pay for its use of Arbutus's technology in a vaccine that has earned Moderna billions of dollars in profits.

ANSWER: Moderna admits that it had previously licensed certain patents (including the '069 Patent) from Acuitas Biotherapeutics ("Acuitas"). Specifically, as part of a November 12, 2012 agreement, Protiva, then a wholly owned subsidiary of Arbutus, licensed patents for LNP technology (including the '069 Patent) to Acuitas. In 2015 and 2016, Acuitas sublicensed certain Protiva/Arbutus LNP patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, Respiratory Syncytial Virus ("RSV"), and Zika virus. Moderna further admits that it filed *inter partes* review petitions challenging the '069 and '435 Patents (as well as the unasserted '127 Patent) before the United States Patent and Trademark Office. Moderna denies the remaining allegations in Paragraph 6.

7. Moderna's intransigence has forced Arbutus and Genevant, a company spearheaded by former Arbutus scientists, to bring this infringement action. Plaintiffs are proud that their LNP technology has had such a profound impact on the heroic fight against the COVID-19 pandemic, and they do not seek to impede by an injunction or otherwise the production or distribution of Moderna's COVID-19 vaccine, including boosters. All Plaintiffs seek is the compensation due to them under the patent laws of the United States and as a matter of simple fairness.

ANSWER: Insofar as Paragraph 7 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 7.

NATURE OF THE ACTION

8. This is a civil action under the patent laws of the United States, 35 U.S.C. § 101 *et seq.,* seeking damages for Moderna's infringing manufacture, use, sale, offer for sale, and/or importation of, and/or the supplying from the United States of a component or all or a substantial portion of the components of, its mRNA-1273 COVID-19 mRNA LNP vaccine product ("Moderna's COVID- 19 vaccine") or any supplemental or booster COVID-19 mRNA LNP vaccine product (collectively, the "Accused Product").

ANSWER: Insofar as Paragraph 8 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Plaintiffs' Amended Complaint purports to be an action under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, in connection with Moderna's manufacture, use, sale, offer for sale, and/or importation of its COVID-19 Vaccine. Moderna denies the remaining allegations in Paragraph 8.

9. As alleged herein, the manufacture, use, sale, offer to sell, and/or importation of the Accused Product, and/or the supplying from the United States of a component or all or a substantial portion of the components of the Accused Product infringes or will infringe, actively induces or will actively induce infringement of, or contributes or will contribute to the infringement of, one or more claims of the following patents relating to nucleic acid-lipid particles, compositions thereof, and their use to deliver nucleic acid-based medicines: U.S. Patent Nos. 8,058,069 (Exhibit A), 8,492,359 (Exhibit B), 8,822,668 (Exhibit C), 9,364,435 (Exhibit D), 9,504,651 (Exhibit E), and 11,141,378 (Exhibit F) (collectively, the "Asserted Patents"). At all relevant times, Arbutus owned the Asserted Patents and licensed exclusive rights to sublicense, practice, and sue for infringement of them to Genevant in certain fields of use that include the vaccine application at issue in this Complaint, with certain exceptions not relevant here (hereinafter, Genevant's "Exclusive Rights").

ANSWER: Insofar as Paragraph 9 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 9 and therefore denies them.

THE PARTIES

10. Plaintiff Arbutus Biopharma Corporation is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974. The company's research and development efforts include discovering, developing, and commercializing a cure for chronic hepatitis B virus, as well as drug discovery and development efforts for treating coronaviruses, including SARS-CoV-2, which causes COVID-19.

ANSWER: Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 10 and therefore denies them.

11. Plaintiff Genevant Sciences GmbH is a company organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. Genevant is a technology-focused nucleic acid delivery solutions company with cutting-edge LNP platforms. Genevant owns or licenses the industry's most important LNP intellectual property-that of Arbutus-and has decades of experience and expertise in nucleic acid

drug delivery and development. Genevant, together with its affiliated companies, maintains offices in Cambridge, Massachusetts and Vancouver, British Columbia, Canada. Genevant's mission is to utilize its LNP and other technologies to deliver innovative new medicines that use mRNA or other nucleic acids.

ANSWER: Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 11 and therefore denies them.

12. Defendant Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. Moderna, Inc., itself and through its subsidiary ModernaTX, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells vaccines and other medicines in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

ANSWER: Moderna admits that Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. Moderna denies the remaining allegations in Paragraph 12.

13. Defendant ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc. (collectively, "Moderna"). ModernaTX, Inc. is also a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. ModernaTX, Inc. develops, manufactures, imports, markets, distributes, offers to sell, and/or sells vaccines and other medicines in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

ANSWER: Moderna admits that ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc. Moderna further admits that ModernaTX, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 200 Technology Square, Cambridge, Massachusetts, 02139. Moderna denies the remaining allegations in Paragraph 13.

JURISDICTION AND VENUE

A. Subject-Matter Jurisdiction

14. Because this is an action for infringement under the patent laws of the United States, Title 35 of the United States Code, the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Insofar as Paragraph 14 contains legal conclusions, no response is required. To the extent that a response is required, Moderna does not contest that the Court has subject matter jurisdiction over this action.

B. Personal Jurisdiction

15. This Court has personal jurisdiction over Moderna because, among other things, Moderna, Inc. and ModernaTX, Inc. have purposefully availed themselves of the benefits and protections of Delaware's laws such that they should reasonably anticipate being haled into court here. Because Defendants are organized and exist under the laws of Delaware, are qualified to do business in Delaware, and have appointed registered agents for service of process in Delaware, Moderna, Inc. and ModernaTX, Inc. have consented to general jurisdiction in Delaware.

ANSWER: Insofar as Paragraph 15 contains legal conclusions, no response is required. To the extent that a response is required, Moderna does not contest the Court has personal jurisdiction over Moderna for purposes of this action only. Moderna denies the remaining allegations in Paragraph 15.

16. Additionally, Moderna, Inc. and ModernaTX, Inc., directly or through others, make, use, induce others to use, offer for sale, and/or sell the Accused Product, and/or a component, combination, or composition constituting a material part of the Accused Product, within the United States, and/or import the same into the United States, including into the District of Delaware. For example, on December 18, 2020, Moderna received Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") for its COVID-19 vaccine to be distributed and administered to people throughout the United States, including in the District of Delaware and, on January 31, 2022, the FDA approved Moderna's Biologics License Application ("BLA") for its COVID-19 vaccine. Upon information and belief, as of February 24, 2022, over 835,000 doses of Moderna's COVID-19 vaccine have been delivered to the State of Delaware.[4] Therefore, Moderna, Inc. and ModernaTX, Inc. transact business within

[4] Delaware Environmental Public Health Tracking Network, Vaccine Tracker, https://myhealthycommunity.dhss.delaware.gov/locations/state/vaccine-tracker (last visited Feb. 25, 2022).

Delaware relating to Plaintiffs' claims and have engaged in systematic and continuous business contacts here.

ANSWER: Moderna admits that Moderna received Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") for its COVID-19 Vaccine on December 18, 2020. Moderna further admits that the FDA approved Moderna's Biologics License Application ("BLA") for its COVID-19 vaccine on January 31, 2022. Moderna lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 16 and therefore denies them.

17. For the above reasons, there is nothing unreasonable or fundamentally unfair about requiring Moderna, Inc. and ModernaTX, Inc. to litigate this action in this District, and the Court has personal jurisdiction over them here.

ANSWER: Insofar as Paragraph 17 contains legal conclusions, no response is required. To the extent that a response is required, Moderna does not contest the Court has personal jurisdiction over Moderna for purposes of this action only. Moderna denies the remaining allegations in Paragraph 17.

C. Venue

18. Venue is proper in this District under 28 U.S.C. §§ 1391(c)(2) and 1400(b) because both Moderna, Inc. and ModernaTX, Inc. are corporations organized and existing under the laws of the State of Delaware and are therefore subject to suit in this District.

ANSWER: Insofar as Paragraph 18 contains legal conclusions, no response is required. To the extent that a response is required, Moderna does not contest that Moderna, Inc. and ModernaTX, Inc. are corporations organized and existing under the laws of the State of Delaware, and that the venue is proper for purposes of this action only.

BACKGROUND

A. How Vaccines Work

19. Viruses are typically small packets of DNA or RNA. If a virus enters a living host cell-for example, after being ingested, transmitted through bodily fluids, or inhaled through a

person's mouth or nose-the virus's DNA or RNA hijacks the cell's machinery and instructs the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus. Left unchecked, the host organism itself can die.

ANSWER: Moderna admits the allegations in Paragraph 19.

20. Although vaccines targeting viruses have different mechanisms of action, they traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection, but nonetheless retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus if it invades in the future.

ANSWER: Moderna admits the allegations in Paragraph 20.

B. Nucleic Acid Medicines and Delivery Technologies

21. Moderna's COVID-19 vaccine belongs to a new class of medicines that deliver nucleic acids into the cells of the body to treat diseases or, in the case of Moderna's COVID-19 vaccine, to trigger an immune response to protect a person from future infection.

ANSWER: Moderna admits the allegations in Paragraph 21.

22. Nucleic acids are molecules that encode the genetic information essential to sustain all forms of life. One type of nucleic acid is deoxyribonucleic acid, or "DNA," which is found in our chromosomes. In humans, each person (except identical twins) has a unique set of genetic information in the "genes" within his or her chromosomes. Among other things, these genes spell out the instructions for producing proteins that make our cells and bodies function.

ANSWER: Moderna admits the allegations in Paragraph 22.

23. In order to make the protein encoded by a particular gene, the cell first converts the genetic code in the gene's DNA into another type of nucleic acid known as messenger ribonucleic acid, or "mRNA." mRNA is effectively a copy of the portion of DNA that the cell's protein-making machinery uses as a blueprint to assemble the protein encoded by the gene.

ANSWER: Moderna admits the allegations in Paragraph 23.

24. Vaccines and other medicines using ribonucleic acid, or "RNA," technologies are an emerging frontier with the potential to revolutionize medicine. RNA-based medicines can employ a type of RNA called small interfering RNA ("siRNA") to treat certain diseases by interfering with the expression of unwanted proteins to reduce the amounts produced-a process called RNA interference ("RNAi"). RNA-based medicines also can employ mRNA to cause or increase the production of certain proteins. mRNA vaccines, for example, cause cells to express a protein (or a piece of a protein) that is normally found on a particular tumor or that is part of a particular virus. The presence of that protein (or piece of a protein) teaches the body's immune system to recognize it if it is encountered in the future and destroy it. These and other RNA-based

medicines hold great promise for addressing many previously intractable diseases and, as in the present circumstances, new viruses that cause or threaten worldwide pandemics.

ANSWER: Moderna admits that administration of its COVID-19 Vaccine results in expression of the spike protein, which prompts the body's immune system to recognize it and trigger an immune response. Moderna also admits that mRNA vaccines like the COVID-19 Vaccine hold great promise for addressing many previously intractable diseases. Moderna denies the remaining allegations in Paragraph 24.

25. Despite their promise, however, RNA-based medicines have been difficult to develop. By their nature, RNA molecules are fragile. Without adequate protection, RNA molecules are susceptible to degradation in the body, and, if and when they get to a cell, cannot cross the cell membrane to enter the cell. For decades, the need for an effective delivery technology had been the most significant challenge in the development of RNA-based products. In particular, without the means to protect mRNA and facilitate its entry into target cells, mRNA-based vaccines and other medicines have been ineffective.

ANSWER: Moderna admits that mRNA-based medicines rely on an effective delivery technology to protect nucleic acids from degradation and enable mRNA to reach target membranes. Moderna denies the remaining allegations in Paragraph 25.

26. Indeed, functional RNA-based medicines eluded researchers until the pioneering work by Arbutus scientists, many now at Genevant companies, resulting in the discovery and development of the leading nucleic acid delivery technology in use today. Decades ago, a group of ambitious research scientists working at a predecessor company to Arbutus began to tackle the nucleic acid delivery problem that had long stymied the field. Years of tireless effort by these scientists resulted in a solution to the problem. The solution was LNP technology that relies on fat-like molecules called lipids that encapsulate and protect nucleic acids like mRNA from degradation in the body and enable them to cross cell membranes. Once inside a cell, the LNP releases the nucleic acid it encapsulates so that, in the case of an mRNA vaccine for example, the nucleic acid can express the protein it encodes.

ANSWER: Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26 and therefore denies them.

27. The lipid components of the Arbutus technology include: structural lipids, such as phospholipids and cholesterol; "cationic" (positive charge-bearing) lipids, including "ionizable" lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, which are lipids attached to a polymer such as polyethyleneglycol ("PEG"). Arbutus scientists discovered that

nucleic acid-lipid particles combining particular lipid components in particular ratios could achieve much more effective delivery of nucleic acids through cell membranes and into cells.

ANSWER: Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27 and therefore denies them.

28. These Arbutus scientists spent more than a decade researching and developing this nucleic acid-lipid delivery technology. Their efforts led to the first FDA-approved RNA- based therapeutic in the form of a drug called Onpattro®, an RNAi treatment for a form of amyloidosis, a rare disease that causes certain proteins to accumulate in organs. The company that developed Onpattro®, Alnylam Pharmaceuticals, did so under an LNP license from Arbutus and received FDA approval in August 2018. Building on this initial success, Arbutus has granted licenses to its LNP technology to other companies, and Genevant now has several ongoing LNP product development collaborations, some directed to COVID-19 and some directed to other diseases and disorders. Several entities developing mRNA-LNP vaccines against COVID-19 have come to Genevant for a license to Arbutus's technology, including companies that have produced promising candidates in clinical trials. And Genevant's COVID- 19 development collaborations include efforts to provide a vaccine to parts of the developing world.

ANSWER: Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28 and therefore denies them.

C. The United States Awards Patents Recognizing Arbutus's Innovations

29. In recognition of Arbutus's extensive and groundbreaking research and development efforts, the United States Patent and Trademark Office has granted several families of patents claiming nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods of using them. The Asserted Patents are among them:

a. U.S. Patent No. 8,058,069, "Lipid Formulations for Nucleic Acid Delivery," issued on November 15, 2011 (the "'069 Patent").
b. U.S. Patent No. 8,492,359, "Lipid Formulations for Nucleic Acid Delivery," issued on July 23, 2013 (the "'359 Patent").
c. U.S. Patent No. 8,822,668, "Lipid Formulations for Nucleic Acid Delivery," issued on September 2, 2014 (the "'668 Patent").
d. U.S. Patent No. 9,364,435, "Lipid Formulations for Nucleic Acid Delivery," issued on June 14, 2016 (the "'435 Patent").
e. U.S. Patent No. 9,504,651, "Lipid Compositions for Nucleic Acid Delivery," issued on November 29, 2016 (the "'651 Patent").
f. U.S. Patent No. 11,141,378, "Lipid Formulations for Nucleic Acid Delivery," issued on October 12, 2021 (the "'378 Patent").

ANSWER: Moderna admits the following patents were applied for and granted by the United States Patent and Trademark Office: U.S. Patent No. 8,058,069, which states on its face

that its title is "Lipid Formulations for Nucleic Acid Delivery" with an issue date of November 15, 2011 (the "'069 Patent"); U.S. Patent No. 8,492,359, which states on its face its title is "Lipid Formulations for Nucleic Acid Delivery" with an issue date of July 23, 2013 (the "'359 Patent"); U.S. Patent No. 8,822,668, which states on its face its title is "Lipid Formulations for Nucleic Acid Delivery" with an issue date of September 2, 2014 (the "'668 Patent"); U.S. Patent No. 9,364,435, which states on its face its title is "Lipid Formulations for Nucleic Acid Delivery" with an issue date of June 14, 2016 (the "'435 Patent"); U.S. Patent No. 9,504,651, which states on its face its title is "Lipid Compositions for Nucleic Acid Delivery" with an issue date of November 29, 2016 (the "'651 Patent"); U.S. Patent No. 9,504,651, which states on its face its title is "Lipid Compositions for Nucleic Acid Delivery" with an issue date of November 29, 2016 (the "'651 Patent") (collectively, the "Asserted Patents"). Moderna denies the remaining allegations in Paragraph 29.

30. True and correct copies of the Asserted Patents are attached hereto as Exhibits A through F. All are valid and enforceable under United States patent laws. All are assigned to and owned by Arbutus, and, at all times since Arbutus and Genevant entered into a license agreement, Genevant has held Exclusive Rights to all of the Asserted Patents in various fields of use including the vaccine application at issue here. Under the terms of the license, Genevant's Exclusive Rights include the right to sue for the infringement alleged in this Complaint.

ANSWER: Moderna admits that Amended Complaint Exhibits A through F purport to be copies of the Asserted Patents. Moderna lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in Paragraph 30 and therefore denies them.

D. Moderna's Knowledge of, and Background with, the Asserted Patents

31. Moderna has been on actual notice of Arbutus' patents since before its development of the Accused Product and has knowingly used Arbutus's technology as an essential component of its nucleic acid products and product candidates, including its COVID-19 vaccine.

ANSWER: Moderna admits that Moderna was aware of the existence of certain Arbutus patents prior to its development of the COVID-19 Vaccine. Moderna denies the remaining allegations in Paragraph 31.

32. Years before the COVID-19 pandemic, Moderna recognized that Arbutus's LNP technology could fuel its own work in RNA-based vaccines and other medicines. Accordingly, in or about May 2015, Moderna attempted to acquire rights to Arbutus's LNP delivery technology for four specific viral targets (none of which is COVID-19) through sublicense from a Canadian company called Acuitas Therapeutics. Although Acuitas had licensed Arbutus's LNP technology in 2012, its license agreement expressly limited Acuitas's ability to grant sublicenses. That limitation prohibited Acuitas from granting the sublicense that it granted to Moderna.

ANSWER: Moderna admits that Protiva licensed certain patents (including the '069 Patent) to Acuitas, and that in 2015 and 2016, Acuitas sublicensed those patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, RSV, and Zika virus. Moderna denies the remaining allegations in Paragraph 32.

33. In August 2016, after learning of the Moderna-Acuitas sublicense agreements, Arbutus notified Acuitas of material breach. In October 2016, Acuitas filed suit in the Supreme Court of British Columbia seeking to prevent Arbutus from terminating the Arbutus-Acuitas agreement. Arbutus counterclaimed for a declaration that the license had been terminated and sought an injunction barring Acuitas from further sublicensing Arbutus's LNP technology.

ANSWER: Moderna admits that by letter of August 29, 2016, Arbutus stated that it intended to terminate the Arbutus-Acuitas agreement, alleging that Acuitas was in material breach due to sublicenses to Moderna, under which Arbutus had received milestone payments. Moderna admits that in October 2016, Acuitas filed a lawsuit in the Supreme Court of British Columbia, seeking an order that Arbutus specifically perform its obligations under the Arbutus-Acuitas agreement. Moderna further admits that Arbutus counterclaimed for a declaration that the Arbutus-Acuitas agreement had been terminated and sought an injunction barring Acuitas from further sublicensing Arbutus's LNP technology. Moderna denies the remaining allegations in Paragraph 33.

34. In February 2018, Arbutus and Acuitas settled their dispute. The settlement agreement provided that Acuitas no longer could use Arbutus's LNP technology, with the four specific sublicenses to Moderna for vaccines targeting specific viruses remaining in effect. SARS-CoV-2, the virus that causes COVID-19 and the target of the vaccine accused of infringement in this Complaint, is not among the surviving sublicenses.

ANSWER: Moderna lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34 and therefore denies them.

35. Deprived of a broad license to Arbutus's valuable LNP technology and hoping to make unrestricted use of that technology without having to pay royalties, Moderna began filing *inter partes* review ("IPR") petitions requesting that the Patent and Trademark Office cancel certain of Arbutus's patents, including some asserted here.

ANSWER: Moderna admits that, in light of Arbutus' aggressive stance regarding the scope of its patent portfolio, Moderna filed *inter partes* review petitions challenging three Arbutus patents before the United States Patent and Trademark Office, including against the '069 and '435 Patents asserted here. Moderna denies the remaining allegations in Paragraph 35.

36. Moderna's first IPR petition, filed in February 2018, challenged Arbutus's U.S. Patent No. 9,404,127 ("the '127 Patent"), which, like the Asserted Patents, is directed to Arbutus's LNP technology. The Patent Trial and Appeal Board ("PTAB") ruled that all claims of the '127 Patent should be cancelled. An appeal of that decision remains pending before the United States Court of Appeals for the Federal Circuit.

ANSWER: Moderna admits that Moderna filed an *inter partes* review petition in February 2018 against all claims of the '127 Patent. Moderna admits that the Patent Trial and Appeal Board ("PTAB") agreed with Moderna that all claims of the '127 Patent are unpatentable, and that an appeal of that decision is pending before the United States Court of Appeals for the Federal Circuit as of today. Moderna denies the remaining allegations in Paragraph 36.

37. Moderna's IPRs against the Asserted Patents were less successful. Its second IPR petition, filed in March 2018, ended with the PTAB rejecting Moderna's arguments challenging the validity of ten of the '435 Patent's twenty claims. Moderna challenged that ruling on appeal,

but in a December 2021 decision, the United States Court of Appeals for the Federal Circuit dismissed Moderna's appeal for lack of standing.[5]

ANSWER: Moderna admits that Moderna filed an *inter partes* review petition in March 2018 against all claims of the '435 Patent. Moderna further admits that the PTAB determined that ten of the twenty claims of the '435 Patent were unpatentable, while maintaining the remaining ten claims as not unpatentable. Moderna further admits that it filed an appeal challenging the PTAB's decision that these remaining ten claims were not unpatentable. Moderna further admits that Arbutus filed a cross-appeal challenging the PTAB's decision regarding the ten claims found unpatentable. Moderna further admits that in December 2021, the United States Court of Appeals for the Federal Circuit affirmed the PTAB's decision holding ten of the twenty claims of the '435 Patent are unpatentable, while finding Moderna lacked standing to appeal the PTAB's decision for the rest of the claims. Moderna denies the remaining allegations in Paragraph 37.

38. Moderna's third IPR petition, filed in January 2019, was even less successful. The PTAB completely rejected Moderna's challenge to all claims of the '069 Patent, and the United States Court of Appeals for the Federal Circuit affirmed that ruling in December 2021.

ANSWER: Moderna admits that Moderna filed an *inter partes* review petition in January 2019 against all claims of the '069 Patent. Moderna further admits that the PTAB determined that all challenged claims of the '069 Patent were not unpatentable, and that the United States Court of Appeals for the Federal Circuit affirmed the ruling. Moderna denies the remaining allegations in Paragraph 38.

E. Moderna Designs Its COVID-19 Vaccine Over a Single Weekend Aided by the Unauthorized Use of Arbutus's LNP Technology

39. On January 10, 2020, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it for free on the

[5] Arbutus cross-appealed the PTAB's decision, challenging the invalidation of the ten claims of the '435 Patent that were not upheld. On December 1, 2021, the Federal Circuit affirmed the PTAB's decision as to those claims.

internet. This public disclosure revealed the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." With that information in the public domain, researchers around the world were able to begin designing vaccines to target the virus.

ANSWER: Moderna admits that on January 10, 2022, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence, and that this disclosure revealed the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 39 and therefore denies them.

40. Moderna was one of many companies that began work on a vaccine in earnest once the genetic sequence was published.

ANSWER: Moderna admits that in addition to leveraging its decade of research and proprietary technologies, Moderna's work on a vaccine was aided by the publication of the genetic sequence. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 40 and therefore denies them.

41. Relying on Arbutus's LNP technology covered by the Asserted Patents, Moderna was able to begin producing its COVID-19 vaccine *within just a few days* of the SARS-CoV-2 genomic sequence entering the public domain. The design component of the effort was even faster: According to Moderna President Stephen Hoge, "[w]e did it in an hour, and it worked brilliantly."[6] Compared to the timelines of prior vaccine-development efforts, Moderna's accomplishment was unprecedented. In the words of Moderna's CEO Stéphane Bancel, "11 months since the DNA sequence of the virus became available, you will have two approved mRNA vaccines, which has never happened before with any technology. That is amazing."[7]

[6] "Stephen Hoge, MD '03: Tums out, designing a COVID vaccine was easy," UCSF Alumni, *available at* https://alumni.ucsf.edu/stories/stephen-hoge.

[7] Antonio Regalado, "'None of us were ready' to manufacture genetic vaccines for a billion people," MIT Technology Review (December 17, 2020), *available at* https://www.technologyreview.com/2020/12/17/1014989/moderna-vaccine-availability-stephane-bancel-ceo/.

ANSWER: Moderna admits that Moderna brought its COVID-19 vaccine from concept to production in record speed through its own hard work and by building on its decade-plus of research and development perfecting the mRNA biological process and advancing its LNP delivery technology. Moderna admits that the article linked at https://alumni.ucsf.edu/stories/stephen-hoge includes a quote from Moderna President Stephen Hoge that states: "We did it in an hour, and it worked brilliantly. But it was not accomplished in that hour. It was accomplished over the two to three decades of work leading up to that moment, not only at Moderna but across the scientific community." Moderna further admits that the article linked at https://www.technologyreview.com/2020/12/17/1014989/moderna-vaccine-availability-stephane-bancel-ceo/ includes a quote from Moderna's CEO Stéphane Bancel that states: "11 months since the DNA sequence of the virus became available, you will have two approved mRNA vaccines, which has never happened before with any technology. That is amazing." Moderna denies the remaining allegations in Paragraph 41.

42. Moderna's success was chronicled in an article first published online on June 11, 2020, by individuals affiliated with the company and collaborators at the National Institutes of Health. According to this article—the "Moderna/NIH preprint"—"the release of SARS-CoV-2 sequences triggered immediate rapid manufacturing of an mRNA vaccine" by Moderna.[8] Moderna "decide[d] on [the] mRNA-1273 sequence" on January 13, 2020, just three days after the publication of the viral sequence, and "initiate[d] cGMP production" the very next day, on January 14, 2020.[9] On February 24, 2020, Moderna shipped clinical drug product, and, less than a month later, Phase I trials began.[10]

[8] "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness," bioRvix.org (June 11, 2020) *available at* https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1.full.

[9] *Id*.

[10] *Id*.

ANSWER: Moderna admits that the quoted text appears in the articles cited. Moderna admits that it shipped clinical drug product on February 24, 2020. To the extent there are any additional allegations in Paragraph 42, Moderna denies them.

43. Moderna's COVID-19 vaccine could not have been developed, much less on a timeline unprecedented in human history, without Arbutus's proven and patented LNP delivery technology-technology that had transformed vaccine design from a years-long project into one that could be performed within an hour over a January weekend.

ANSWER: Denied.

44. Moderna's co-founder Robert Langer has been quoted as saying "I don't think people realized just how important the delivery systems are ...."[11] LNPs are so crucial to Moderna's mRNA vaccines that Giuseppe Ciaramella, head of infectious diseases at Moderna from 2014 to 2018, called LNPs "the unsung hero of the whole thing,"[12] while Moderna CEO Stéphane Bancel stated in December 2020 that "[w]e always said it is ... about developing the right delivery technology. And this is something that takes years, not two weeks."[13]

ANSWER: Moderna admits that the article available at https://www.bloomberg.com/news/newsletters/2021-03-06/lipids-are-delivering-the- vaccine-revolution includes a quote from Robert Langer saying: "I don't think people realized just how important the delivery systems are to all kinds of medicines," and states that "[w]ithin the LNP for Covid shots, there are two highly specialized lipids. Moderna makes its own versions, while a Vancouver company called Acuitas Therapeutics licenses its technology for the Pfizer-BioNTech shot." Moderna admits that the article available at https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8 includes a quote from Giuseppe Ciaramella,

[11] Tim Loh, "Lipids Are Delivering the Vaccine Revolution," Bloomberg (March 6, 2021), *available at* https://www.bloomberg.com/news/newsletters/2021-03-06/lipids-are-delivering-the-vaccine-revolution.

[12] Ryan Cross, "Without these lipid shells, there would be no mRNA vaccines for COVID-19," C&EN (March 6, 2021), *available at* https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8.

[13] Regalado, *supra* note 7.

head of infectious diseases at Moderna from 2014 to 2018 stating that LNP development "is the unsung hero of the whole thing" for mRNA vaccines, and states: "The off-the-shelf LNP formulations designed for siRNA worked for mRNA occasionally but not very well, says Romesh Subramanian, who led a team at Alexion Pharmaceuticals that worked on mRNA therapies with Moderna from 2014 to 2017. siRNA molecules are like short rods, with two rows of about 20 nucleotides each, he explains. mRNA, in contrast, can easily span thousands of nucleotides, wind into complex shapes, and change the properties of the LNP in ways that are hard to predict. After realizing that MC3 wouldn't cut it for mRNA delivery, Moderna invested significant resources into building a better ionizable lipid. 'There was a group of chemists put on this right away to build novel cationic lipids,' says Ciaramella, the former head of infectious diseases at Moderna. 'It is kind of like a small-molecule drug discovery engine, but on steroids.' The team made about 100 ionizable lipids and introduced ester linkages into the carbon chains of the lipids to help make them more biodegradable, he recalls." Moderna further admits that the article available at https://www.technologyreview.com/2020/12/17/1014989/Moderna-vaccine-availability-stephane-bancel-ceo/ includes a quote from Moderna CEO Stéphane Bancel stating: "[w]e always said it was about developing the right delivery technology. And this is something that takes years, not two weeks" in response to the question "Throughout your company's history, you've been searching for how to apply this technology. Do you think vaccines will remain the killer application?" Moderna denies the remaining allegations in Paragraph 44.

45. The Moderna/NIH preprint detailed Moderna's use of Arbutus's LNP technology and its infringement of the Asserted Patents. The scientists who worked on the vaccine and contributed to the article explained that Moderna's COVID-19 vaccine is composed of mRNA encoding a modified version of the SARS-CoV-2 spike (S) protein that was synthesized, purified, "and encapsulated into lipid nanoparticles (LNP)," with a lipid molar ratio of "50:10:38.5:1.5 (ionizable lipid:DSPC:cholesterol:PEG-lipid)." Specifically, the Moderna/NIH preprint indicates that the Accused Product includes lipid particles comprising the following lipids in the following ratio: 50 mol % of an ionizable lipid that is cationic; 10 mol % of a phospholipid (DSPC); 38.5

mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles (PEG-lipid).

ANSWER: Moderna admits that the BioRvix preprint titled "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness" contains the quoted text in Paragraph 45. Moderna states that the preprint article does not describe the lipid ratio used in commercial formulations of Moderna's COVID-19 Vaccine. Moderna denies the remaining allegations in Paragraph 45.

46. These components are within the ranges of, among other claims of the Asserted Patents, Claim 1 of Arbutus's '069 Patent, which recites a "nucleic acid-lipid particle comprising (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle: (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol % to 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

ANSWER: Insofar as Paragraph 46 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 46.

47. A month after the Moderna/NIH preprint appeared, the PTAB rejected Moderna's IPR challenge to the '069 Patent in its entirety, triggering a ten percent drop in Moderna's share price in a single day. Although Moderna promptly issued public statements denying any infringement, it has been conspicuously silent about what LNP technology is used in its vaccine, if not what is described by its own co-authors in the Moderna/NIH preprint. Moderna has not requested retraction of the Moderna/NIH preprint or otherwise submitted a correction of it. Instead, when it came time to publish the official version of that preprint in the scientific publication *Nature,* it simply excised the relevant details about the LNP technology it was using.

ANSWER: Moderna admits that Moderna's stock price fell 10% on the day the PTAB's final written decision concerning Moderna' *inter partes* review challenge to the '069 Patent issued. Moderna further admits that it has not requested retraction or submitted a correction to the BioRvix preprint titled "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness." Moderna states that the published version of the BioRvix preprint in *Nature* does

not describe the lipids ratio used in preclinical rodent studies. Moderna denies the remaining allegations in Paragraph 47.

48. Nonetheless, another preclinical study of Moderna's COVID-19 vaccine, authored by Corbett et al. and published on the website of *The New England Journal of Medicine* on July 28, 2020, confirmed that the mRNA was encapsulated in an LNP "as described previously" and cited a prior Moderna publication that discloses the same lipid molar ratio as the Moderna/NIH preprint.[14] Four of the article's authors were affiliated with Moderna at the time of the article's publication. Moderna has not requested retraction of the Corbett 2020 *The New England Journal of Medicine* article or otherwise submitted a correction of the Corbett 2020 *The New England Journal of Medicine* article.

ANSWER: Moderna admits that the article entitled "Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates" states in the subsection "Vaccine mRNA and Lipid Nanoparticle Production" that "[w]e synthesized a sequence-optimized mRNA encoding prefusion-stabilized SARS-CoV-2 S-2P protein in vitro. The mRNA was purified by oligo-dT affinity purification and encapsulated in a lipid nanoparticle through a modified ethanol-drop nanoprecipitation process, as described previously." Moderna further admits that the previous sentence cites Hassett et al., "Optimization of Lipid Nanoparticles for Intramuscular Administration of mRNA Vaccines," *Mol. Ther. Nucl. Acids* 15:1-11, 8 (2019). Moderna further admits that it has not requested retraction or submitted a correction to the the article entitled "Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates." Moderna denies the remaining allegations in Paragraph 48.

49. What is more, on May 14, 2021, Moderna submitted an international Patent application titled "Coronavirus RNA Vaccines and Methods of Use," which published on August 12, 2021, as International Patent Publication WO 2021/159130. In that application, "Example 1:Phase 1 Clinical Trial" identifies the specific ionizable lipid used in the Phase I clinical trial of Moderna's vaccine as "heptadecan-9-yl 8 ((2 hydroxyethyl)(6 oxo 6-(undecyloxy)hexyl) amino)octanoate 20," also known as SM-102, which in its ionized state is positively charged

[14] *See* Corbett et al., "Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates," NEJM383;16:1544-1555, 1546 (2020) (citing Hassett et al., "Optimization of Lipid Nanoparticles for Intramuscular Administration of mRNA Vaccines," *Mol. Ther. Nucl. Acids* 15:1-11, 8 (2019)), *available at* https://www.nejm.org/doi/full/10.1056/nejmoa2024671#.

(cationic). [15] Example 1 also recites that the particles used in the Phase I clinical trial of Moderna's vaccine are prepared with the same lipid molar ratio identified in the Moderna/NIH preprint, i.e.: 50 mol % of an ionizable lipid that is cationic; 10 mol % of a phospholipid (DSPC); 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles (PEG-lipid).[16]

ANSWER: Moderna admits that on May 14, 2021, Moderna submitted an international Patent application titled "Coronavirus RNA Vaccines and Methods of Use," which published on August 12, 2021, as International Patent Publication WO 2021/159130. Moderna further admits that Example 1 in WO 2021/159130 states that "[t]he SARS-CoV-2 mRNA vaccine (SEQ ID NO: 6, ORF SEQ ID NO: 7, encoding SEQ ID NO: 8) was a lipid nanoparticle (LNP) dispersion of an mRNA encoding the prefusion stabilized spike protein SARS-CoV-2 formulated in LNPs composed of four (4) lipids (50 mol% ionizable lipid heptadecan-9-yl 8 ((2 hydroxy ethyl) (6 oxo 6-(undecyloxy)hexyl)amino)octanoate (Compound 1); 10 mol% 1,2 distearoyl sn glycero-3 phosphocholine (DSPC); 38.5 mol% cholesterol; and 1.5 mol% l-monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000 DMG))." Moderna denies the remaining allegations in Paragraph 49.

50. Notwithstanding its repeated statements in published articles and its patent application, Moderna publicly denied infringement of Arbutus's patents, ostensibly on the basis that the LNPs in Moderna's COVID-19 vaccine manufactured and sold initially on the basis of EUA and now with full FDA approval differed from the LNPs in its Phase I clinical trial. But while Moderna was denying infringement in public statements, its Senior Vice President and Deputy General Counsel, Shaun Ryan, submitted on February 23, 2021, a sworn statement under penalty

[15] *See* International Patent Publication WO 2021/159130 at 49.

[16] *See id.* ("The SARS-CoV-2 mRNA vaccine...was a lipid nanoparticle (LNP) dispersion of an mRNA encoding the prefusion stabilized spike protein SARS-CoV-2 formulated in LNPs composed of four (4) lipids (50 mol% ionizable lipid heptadecan-9-yl 8 ((2 hydroxyethyl)(6 oxo 6-(undecyloxy)hexyl)amino)octanoate 20 (Compound 1); 10 mol% 1,2 distearoyl sn glycero-3 phosphocholine (DSPC); 38.5 mol% cholesterol; and 1.5 mol% l-monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000 DMG)).")

of perjury in support of one of its IPR appeals to the United States Court of Appeals for the Federal Circuit. In that sworn declaration, he stated that the "lipid carrier particle" used in its Phase I study-described in the Moderna/NIH preprint and WO 2021/159130 as being within the scope at least of Claim 1 of the '069 Patent is the same as the one that was "ultimately approved" for use in its product.[17]

ANSWER: Moderna states that Shaun Ryan, Senior Vice President and Deputy General Counsel at Moderna, stated in a sworn statement under penalty of perjury submitted in support of Moderna's *inter partes* review appeal for the '069 Patent that: "Shortly after the SARS-CoV-2 genetic sequence was determined in January 2020 by the Chinese government, Moderna developed mRNA-1273, a lipid-nanoparticle (LNP)–encapsulated mRNA vaccine expressing the prefusion-stabilized spike glycoprotein. mRNA-1273 uses an mRNA payload delivered by a lipid carrier particle, which includes an ionizable lipid, DSPC, cholesterol, and a PEG-lipid in a ratio that falls outside the ranges claimed in Arbutus's U.S. Patent No. 8,058,069 ('the '069 patent')." Moderna further admits that Mr. Ryan's sworn statement further states that "Moderna and its government partners began a Phase 1 study for mRNA-1273 using the payload and lipid carrier particle ultimately approved." Moderna denies the remaining allegations in Paragraph 50.

51. Distribution of the Accused Product and its administration to persons in the United States and around the world commenced immediately after the FDA granted Moderna's COVID-19 vaccine an EUA on December 18, 2020. In 2021, Moderna shipped 807 million doses.[18] As of February 24, 2022, Moderna had signed advanced purchase agreements worth approximately $19 billion for all of 2022.[19] As of May 6, 2021, Moderna had signed advance purchase agreements

[17] Declaration of Shaun Ryan, Mot. to Supplement the Record to Provide Evidence of Standing, Dkt. No. 18, 11-12 ¶¶ 3-4, *Moderna TX, Inc. v. Arbutus Biopharma Corp.,* No. 2020-2329 (Fed. Cir.).

[18] Press Release, Moderna, Moderna Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Business Updates (Feb. 24, 2022), https://investors.modernatx.com/news/news-details/2022/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates/default.aspx.

[19] *Id*.

covering more than one billion doses.[20] And from December 18, 2020, through February 24, 2022, more than 200 million doses of Moderna's COVID-19 vaccine had been administered to people throughout the United States.[21] Moderna's vaccine doses made in the United States and administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. All of the manufacturing and sales of vaccines distributed in the United States were for the benefit of the American public. Millions more doses, including doses made in the United States, have been administered abroad.

ANSWER: Moderna admits that the FDA granted EUA for its COVID-19 Vaccine on December 18, 2020. Moderna admits that it shipped 807 million doses of its COVID-19 Vaccine in 2021. Moderna admits that as of February 24, 2022, it had signed advanced purchase agreements worth approximately $19 billion for all of 2022. Moderna admits that as of May 6, 2021, Moderna had signed advance purchase agreements covering more than one billion COVID-19 Vaccine doses. Moderna admits that from December 18, 2020 through February 24, 2022, more than 200 million doses of Moderna's COVID-19 Vaccine had been administered to people throughout the United States. Moderna denies the remaining allegations in Paragraph 51.

52. On June 1, 2021, Moderna announced that it had initiated the FDA process for a BLA-i.e., for the full-fledged licensure of its COVID-19 vaccine. As of February 24, 2022, Moderna's COVID-19 vaccine had received at least emergency authorization from more than 70 countries,[22] including Canada, Israel, the United Kingdom, Switzerland, Singapore, Qatar,

[20] Press Release, Moderna, Moderna Reports First Quarter Fiscal Year 2021 Financial Results and Provides Business Updates (May 6, 2021), https://investors.Modernatx.com/news- releases/news-release-details/Moderna-reports-first-quarter-fiscal-year-2021-financial-results.

[21] COVID-19 Vaccinations in the United States, CDC (last visited Feb. 25, 2022), https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-tota1-admin-rate-total.

[22] Press Release, Moderna, Moderna Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Business Updates (Feb. 24, 2022), https://investors.Modernatx.com/news/news-details/2022/Moderna-Reports-Fourth-Quarter-and-Fiscal-Year-2021-Financial-Results-and-Provides-Business-Updates/default.aspx.

Taiwan, and the Philippines, as well as from the European Union.[23] On January 31, 2022, the FDA approved Moderna's BLA for its COVID-19 vaccine.[24]

ANSWER: Moderna admits the allegations in Paragraph 52.

53. In May 2021, Moderna announced that it had begun exporting from the United States doses of its COVID-19 vaccine that were manufactured in facilities in the United States.[25] Those doses were made in the United States and sold to foreign governments or other foreign entities for the benefit of individuals outside the United States.

ANSWER: Moderna admits that as of May 2021, Moderna had begun shipping COVID-19 Vaccine supply abroad from its U.S. production facilities. Moderna denies the remaining allegations in Paragraph 53.

54. Moderna also has contracted with a number of companies around the world to manufacture its COVID-19 vaccine.[26] This includes several companies that employ facilities in the United States to manufacture Moderna's vaccine.[27]

ANSWER: Moderna admits the allegations in Paragraph 54.

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[23] *See id*.

[24] Press Release, Moderna, Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax (Jan. 31, 2022), https://investors. Modernatx.com/news/news'-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

[25] Moderna Reply Br. at 22, Dkt. No. 41, *Moderna TX, Inc. v. Arbutus Biopharma Corp.* (Fed. Cir. No. 2020-2329) (citing Vaccine Exports From U.S. Accelerate as Moderna Ships Abroad, Bloomberg.com (May 20, 2021), https://www.bloomberg.com/news/articles/2021-05-20/moderna-starts-shipping-vaccine-from-u-s-boosting-shot-exports).

[26] *See, e.g.,* Press Release, Moderna, Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus (May 1, 2020), https://investors.Modernatx.com/news-releases/news-release-details/Moderna-and-lonza-announce-worldwide-strategic-collaboration.

[27] *Id.; see also, e.g.,* Press Release, Moderna, Baxter BioPharma Solutions and Moderna Announce Agreement for Fill/Finish Manufacturing of the Moderna COVID-19 Vaccine in the U.S. (Mar. 8, 2021), https://investors.Modernatx.com/news-releases/news-release-details/baxter- biopharma-solutions-and-moderna-announce-agreement.

55. Moderna chose to contract with companies to establish sites outside the United States that would combine the components of its COVID-19 vaccine, which it described as "independent US and international supply chains."[28]

ANSWER: Moderna admits that its manufacturing supply chain includes sites outside the United States. Moderna denies the remaining allegations in Paragraph 55.

56. However, these sites outside the United States still relied on manufacturing in the United States by Moderna or at Moderna's direction to supply them components of the Accused Product. Moderna manufactured the components of its infringing product—mRNA [redacted]—in the United States and then supplied them, or cause them to be supplied, outside of the United States to be combined to make the finished COVID-19 vaccine.[29] These components constitute a substantial portion of Moderna's COVID-19 vaccine and were combined outside the United States at Moderna's direction.

ANSWER: Insofar as Paragraph 56 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that its manufacturing supply chain includes sites inside and outside the United States. Moderna denies the remaining allegations in Paragraph 56.

57. Moderna's COVID-19 vaccine is [redacted]:[30]

[28] MRNA-GEN-00854857.

[29] MRNA-GEN-01424228.

[30] MRNA-GEN-00031755 at -761.

ANSWER: Moderna admits that MRNA-GEN-00031755–784 includes the figure excerpted in Paragraph 57 at MRNA-GEN-00031761. Moderna denies the remaining allegations in Paragraph 57.

58. These components are especially made or adapted for Moderna's COVID-19 vaccine. The mRNA component encodes a modified version of the SARS-CoV-2 spike (S) protein, which is specifically designed for use in the COVID-19 vaccine. [redacted] Neither component is a staple item and neither is used in any commercial product other than Moderna's COVID-19 vaccine.

ANSWER: Insofar as Paragraph 58 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Moderna's COVID-19 vaccine contains nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2. Moderna denies the remaining allegations in Paragraph 58.

F. Arbutus and Genevant Attempt to Negotiate a License with Moderna

59. Plaintiffs tried to avoid the need to file this lawsuit.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 59 and therefore denies them.

60. Many companies have paid Plaintiffs for a license to use the breakthrough LNP technology at issue here, including several companies developing COVID-19 vaccines and several

other companies with which Genevant has ongoing development collaborations. The research and development facilitated by these and other licenses has resulted in product candidates across a variety of conditions.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 60 and therefore denies them.

61. Plaintiffs would have preferred to resolve their dispute with Moderna with a mutually acceptable license from Genevant. And Plaintiffs have long sought to do just that. In proposing such a license, Plaintiffs did not wish to minimize the importance of Moderna's extensive efforts to manufacture and distribute billions of doses of its COVID-19 vaccine in the midst of a global pandemic. Those efforts have been vitally important and have saved countless lives. Rather, Plaintiffs sought only the fair and reasonable compensation to which they are entitled by law for their contributions to Moderna's COVID-19 vaccine-contributions that were the product of decades of pioneering work by Arbutus scientists, many now at Genevant companies, including during periods when it was uncertain whether mRNA vaccines could ultimately be made to work.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 61 and therefore denies them.

62. Unfortunately, Moderna has consistently declined to engage meaningfully in licensing discussion, necessitating this lawsuit.

ANSWER: Without waiving its right to object to the admissibility of any evidence of discussions between Moderna and Plaintiffs, should all or part of any writing or recorded statement relating to such discussions be introduced, as well as the right to introduce the entire writing or any related writing or recorded statement under Federal Rule of Evidence 106, Moderna admits that it declined Arbutus's licensing offers and further that, as stated above, Moderna's COVID-19 Vaccine does not rely on the technology claimed in Arbutus's patents. Moderna denies the remaining allegations in Paragraph 62.

63. On November 23, 2020, Arbutus and Genevant sent Moderna a letter stating that the Accused Product may infringe claims of each of the then-issued Asserted Patents and offering to discuss the terms of a collaboration or license to further both parties' goal of ending the COVID-19 pandemic. Moderna acknowledged receipt of this letter on November 25, 2020.

ANSWER: Without waiving its right to object to the admissibility of any evidence of discussions between Moderna and Plaintiffs, should all or part of any writing or recorded statement

relating to such discussions be introduced, as well as the right to introduce the entire writing or any related writing or recorded statement under Federal Rule of Evidence 106, Moderna admits that on November 23, 2020, Plaintiffs sent Moderna a letter alleging infringement and offering to license certain Asserted Patents. Moderna further admits that it acknowledged receipt of the letter on November 25, 2020. Moderna denies the remaining allegations in Paragraph 63.

64. On December 10, 2020, Moderna sent a letter to Arbutus and Genevant stating that Moderna was "open to hearing [Genevant's] proposal for a partnership or patent license."

ANSWER: Without waiving its right to object to the admissibility of any evidence of discussions between Moderna and Plaintiffs, should all or part of any writing or recorded statement relating to such discussions be introduced, as well as the right to introduce the entire writing or any related writing or recorded statement under Federal Rule of Evidence 106, Moderna admits the allegations in Paragraph 64.

65. Upon receiving the Arbutus and Genevant proposal, however, Moderna declined to negotiate. Moderna also declined repeated requests to provide samples or non-public documents, even under a confidentiality agreement, to support any assertion that it does not infringe the Asserted Patents, including those in which it invested substantial resources and time to challenge, throughout 2020 and 2021, before the United States Patent and Trademark Office and the United States Court of Appeals for the Federal Circuit.

ANSWER: Without waiving its right to object to the admissibility of any evidence of discussions between Moderna and Plaintiffs, should all or part of any writing or recorded statement relating to such discussions be introduced, as well as the right to introduce the entire writing or any related writing or recorded statement under Federal Rule of Evidence 106, Moderna admits that Moderna declined Plaintiffs' request for highly sensitive technical documents, albeit with a confidentiality agreement in place. Moderna further admits that Moderna declined to engage in further licensing discussion after receiving Plaintiffs' proposed licensing terms, and further that, as stated above, Moderna's COVID-19 Vaccine does not rely on the technology claimed in Arbutus's patents. Moderna denies the remaining allegations in Paragraph 65.

G. Moderna Refuses to Compensate Arbutus and Genevant for Using Their Technology

66. Despite Arbutus and Genevant's repeated efforts, Moderna has refused to take a license from, partner with, or otherwise compensate Plaintiffs for their contribution to Moderna's COVID-19 vaccine. Instead, Moderna continues to infringe the Asserted Patents directly and indirectly, without authority and with actual knowledge of, or reckless disregard for, the fact that its actions constitute infringement of the Asserted Patents.

ANSWER: Without waiving its right to object to the admissibility of any evidence of discussions between Moderna and Plaintiffs, should all or part of any writing or recorded statement relating to such discussions be introduced, as well as the right to introduce the entire writing or any related writing or recorded statement under Federal Rule of Evidence 106, Moderna admits that it declined Arbutus's licensing offers, and further that Moderna's COVID-19 Vaccine does not rely on the technology claimed in Arbutus's patents. Moderna denies the remaining allegations in Paragraph 66.

67. Arbutus and Genevant fully support Moderna's efforts to supply vaccines to people in the United States and worldwide and in no way seek to interfere with those efforts. Accordingly, no injunctive relief is sought in this case.

ANSWER: Moderna admits that no injunctive relief is sought in the Amended Complaint. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 67 and therefore denies them.

68. However, Moderna has made extensive use of, and earned billions in profits exploiting, Arbutus's patented technology, including the technology described and claimed in the Asserted Patents. Moderna's actions have caused harm, and continue to cause harm, to Arbutus and Genevant. Arbutus and Genevant have no choice but to defend their proprietary and patented technology and seek fair and reasonable compensation for the value of their innovation.[31]

[31] The allegations herein are exemplary and without prejudice to Arbutus and Genevant's infringement contentions. In providing these allegations, Arbutus and Genevant do not convey or imply any particular claim constructions or the precise scope of the claims. Arbutus and Genevant's claim construction contentions regarding the meaning and scope of the claim terms will be provided under the Court's scheduling order and this District's Local Rules.

ANSWER: Insofar as Paragraph 68 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 68.[32]

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 8,058,069

69. Paragraphs 1 through 64 are incorporated by reference as if fully set forth herein.

ANSWER: Moderna repeats and incorporates by references it responses to paragraphs 1-68 of the Amended Complaint.

70. The United States Patent and Trademark Office duly and legally issued the '069 Patent to one of Arbutus's predecessor companies on November 15, 2011. The '069 Patent is titled "Novel Lipid Formulations for Nucleic Acid Delivery."

ANSWER: Moderna admits that on November 15, 2011, the United States Patent and Trademark Office issued the '069 Patent, which states on its face that its title is "Novel Lipid Formulations for Nucleic Acid Delivery," but denies that the patent claims patentable work. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 70 and therefore denies them.

71. Arbutus owns, and at all relevant times has owned, the '069 Patent.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 71 and therefore denies them.

72. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '069 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 72 and therefore denies them.

[32] The allegations herein are exemplary and without prejudice to Moderna's invalidity and/or non-infringement contentions (to the extent required by any Scheduling Order). In providing these allegations, Moderna does not convey or imply any particular claim constructions or the precise scope of the claims. Moderna's claim construction contentions regarding the meaning and scope of the claim terms will be provided under the Court's Scheduling Order.

73. Claims of the '069 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

ANSWER: Insofar as Paragraph 73 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 73 and therefore denies them.

74. Moderna has directly infringed and continues to directly infringe claims of the '069 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '069 Patent, without authority or license to do so, during the term of the '069 Patent.

ANSWER: Insofar as Paragraph 74 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 74.

75. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '069 Patent under 35 U.S.C. § 271(b) by encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '069 Patent.

ANSWER: Insofar as Paragraph 75 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 75.

76. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the '069 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '069 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 76 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 76.

77. Moderna has also infringed and continues to infringe the '069 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '069 patent if such combination occurred within the United States.

ANSWER: Insofar as Paragraph 77 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 77.

78. Moderna has also infringed and continues to infringe the '069 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 78 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 78.

79. For example, Claim 1 of the '069 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol % to 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

ANSWER: Moderna admits that Claim 1 of the '069 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol % to 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle." Moderna denies the remaining allegations in Paragraph 79.

80. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Asserted Product is an mRNA which encodes the COVID-19 spike protein.

ANSWER: Insofar as Paragraph 80 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 80.

81. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a phospholipid (DSPC); cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

ANSWER: Insofar as Paragraph 81 contains legal conclusions, no response is required.

To the extent a response is required, Moderna denies the allegations in Paragraph 81.

82. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

ANSWER: Insofar as Paragraph 82 contains legal conclusions, no response is required.

To the extent a response is required, Moderna denies the allegations in Paragraph 82.

83. Moderna has known of the '069 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of, and has actively monitored Arbutus's patent estate, including the '069 Patent.[33] Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents, including the '069 Patent, through *inter partes* review; and Moderna has repeatedly made public representations regarding Arbutus's LNP technology and patents.[34] Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

ANSWER: Insofar as Paragraph 83 contains legal conclusions, no response is required.

To the extent a response is required, Moderna admits that Protiva licensed certain patents for LNP technology (including the '069 Patent) to Acuitas, and that in 2015 and 2016, Acuitas sublicensed

[33] *See, e.g.,* Moderna Mot. at 4-5, Dkt. No. 18, *Moderna TX, Inc. v. Arbutus Biopharma Corp.* (Fed. Cir. No. 2020-2329).

[34] *See, e.g.,* Moderna Mot. at 5, Dkt. No. 18, *Moderna TX, Inc. v. Arbutus Biopharma Corp.* (Fed. Cir. No. 2020-2329); Press Release, Moderna, Statement from Moderna on Patent Trial and Appeal Board (PTAB) Ruling (July 24, 2020), https://investors.Modernatx.com/news-releases/news-release-details/statement-Moderna-Patent-trial-and-appeal-board-ptab-ruling.

certain Protiva/Arbutus LNP patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, RSV, and Zika virus. Moderna further admits that it filed *inter partes* review petitions challenging three Arbutus patents, including the '069 Patent, before the United States Patent and Trademark Office. Moderna further admits that the Moderna press release cited in Paragraph 83, footnote 34 entitled "Statement from Moderna on Patent Trial and Appeal Board (PTAB) Ruling" from July 24, 2020 states: "The recently issued Patent Trial and Appeal Board ruling on the 8,058,069 Patent relates to Moderna's challenge to certain legacy patents held by Arbutus, commenced well before the development of mRNA-1273. These actions were taken by Moderna in response to the longstanding aggressive posture taken by Arbutus and its predecessor company against many developers of nucleic acid-based therapeutics. Through its actions, Moderna successfully overturned one legacy patent held by Arbutus and invalidated the broadest claims of a second one. Moderna's continued development of its proprietary LNP formulation technology and manufacturing processes have advanced well beyond the technology described in these legacy Arbutus patents. Our improved proprietary LNP formula, used to manufacture mRNA-1273, is not covered by the Arbutus patents. Moderna is not aware of any significant intellectual property impediments for any products we intend to commercialize, including mRNA-1273." Moderna denies the remaining allegations in Paragraph 83.

84. Moderna actively and knowingly has infringed the '069 Patent and actively and knowingly has induced infringement of the '069 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA[35] to market and sell its vaccine in the United States with the specific intent

[35] Press Release, Moderna, Moderna Announces Initiation of Rolling Submission of Biologics License Application (BLA) with U.S. FDA for the Moderna COVID-19 Vaccine (June 1, 2021), https://investors.Modernatx.com/news-releases/news-release-details/Moderna-announces-initiation-rolling-submission-biologics; Press Release, Moderna, Moderna Receives Full U.S. FDA Approval for COVID-19 Vaccine Spikevax (Jan. 31, 2022), https://investors.Modernatx.com/news/news-details/2022/Moderna-Receives-Full-U.S.-FDA-Approval-for-COVID-19-Vaccine-Spikevax/default.aspx.

to induce customers to purchase the Accused Product. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad,[36] and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna markets the Accused Product to governments and other entities with the intent for healthcare professionals to administer the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

ANSWER: Insofar as Paragraph 84 contains legal conclusions, no response is required.

Moderna denies the remaining allegations in Paragraph 84.

85. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '069 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '069 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '069 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '069 Patent by administering the Accused Product in the United States.

ANSWER: Insofar as Paragraph 85 contains legal conclusions, no response is required.

To the extent a response is required, Moderna denies the allegations in Paragraph 85.

86. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '069 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying or causing to be supplied from the United States a component or all or a substantial portion of components of the Accused Product.

[36] Press Release, Moderna, Moderna and Lonza Announce Worldwide Strategic Collaboration to Manufacture Moderna's Vaccine (mRNA-1273) Against Novel Coronavirus (May 1, 2020), https://investors.Modernatx.com/news-releases/news-release-details/Moderna-and-lonza-announce-worldwide-strategic-collaboration.

ANSWER: Insofar as Paragraph 86 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 86.

87. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

ANSWER: Insofar as Paragraph 87 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 87.

88. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '069 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '069 Patent.

ANSWER: Insofar as Paragraph 88 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 88.

89. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '069 Patent.

ANSWER: Insofar as Paragraph 89 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 89.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 8,492,359

90. Paragraphs 1 through 83 are incorporated by reference as if fully set forth herein.

ANSWER: Moderna repeats and incorporates by references it responses to paragraphs 1-89 of the Amended Complaint.

91. The United States Patent and Trademark Office duly and legally issued the '359 Patent to one of Arbutus's predecessor companies on July 23, 2013. The '359 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

ANSWER: Moderna admits that on July 23, 2013, the United States Patent and Trademark Office issued the '359 Patent, which states on its face that its title is "Lipid Formulations for Nucleic Acid Delivery," but denies that the patent claims patentable work. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 91 and therefore denies them.

92. Arbutus owns, and at all relevant times has owned, the '359 Patent.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 92 and therefore denies them.

93. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '359 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 93 and therefore denies them.

94. Claims of the '359 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

ANSWER: Insofar as Paragraph 94 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 94 and therefore denies them.

95. Moderna has directly infringed and continues to directly infringe claims of the '359 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '359 Patent, without authority or license to do so, during the term of the '359 Patent.

ANSWER: Insofar as Paragraph 95 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 95.

96. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '359 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '359 Patent.

ANSWER: Insofar as Paragraph 96 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 96.

97. Moderna has contributed, and continues to contribute to the infringement of one or more claims of the '359 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '359 Patent, knowing the same to be especially made or especially adapted for use in the infringement

of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 97 contains legal conclusions, no response is required.

To the extent a response is required, Moderna denies the allegations in Paragraph 97.

98. Moderna has also infringed and continues to infringe the '359 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '359 patent if such combination occurred within the United States.

ANSWER: Insofar as Paragraph 98 contains legal conclusions, no response is required.

To the extent a response is required, Moderna denies the allegations in Paragraph 98.

99. Moderna has also infringed and continues to infringe the '359 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 99 contains legal conclusions, no response is required.

To the extent a response is required, Moderna denies the allegations in Paragraph 99.

100. For example, Claim 1 of the '359 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

ANSWER: Moderna admits that Claim 1 of the '359 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof

comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle." Moderna denies the remaining allegations in Paragraph 100.

101. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

ANSWER: Insofar as Paragraph 101 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 101.

102. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a phospholipid (DSPC); cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

ANSWER: Insofar as Paragraph 102 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 102.

103. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

ANSWER: Insofar as Paragraph 103 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 103.

104. Moderna has known of the '359 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's Patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents through *inter partes* review; and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. The '359 Patent is in the same family as, and is cited on the face of, the '435 Patent that Moderna challenged in *inter partes* review. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

ANSWER: Insofar as Paragraph 104 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Protiva licensed certain patents for LNP technology to Acuitas, and that in 2015 and 2016, Acuitas sublicensed certain Protiva/Arbutus LNP patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, RSV, and Zika virus. Moderna further admits that it filed *inter partes* review petitions challenging three Arbutus patents before the United States Patent and Trademark Office. Moderna further admits that the '359 Patent is in the same family as, and is cited on the face of, the '435 Patent that Moderna challenged in *inter partes* review. Moderna denies the remaining allegations in Paragraph 104.

105. Moderna actively and knowingly has infringed the '359 Patent and actively and knowingly has induced infringement of the '359 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce customers to purchase the Accused Product. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to administer the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

ANSWER: Insofar as Paragraph 105 contains legal conclusions, no response is required. Moderna denies the remaining allegations in Paragraph 105.

106. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '359 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '359 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the

invention of the '359 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '359 Patent by administering the Accused Product in the United States.

ANSWER: Insofar as Paragraph 106 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 106.

107. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '359 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same and/or by supplying a component or all or a substantial portion of components of the Accused Product.

ANSWER: Insofar as Paragraph 107 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 107.

108. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

ANSWER: Insofar as Paragraph 108 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 108.

109. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '359 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '359 Patent.

ANSWER: Insofar as Paragraph 109 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 109.

110. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '359 Patent.

ANSWER: Insofar as Paragraph 110 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 110.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 8,822,668

111. Paragraphs 1 through 102 are incorporated by reference as if fully set forth herein.

ANSWER: Moderna repeats and incorporates by references it responses to paragraphs 1-110 of the Amended Complaint.

112. The United States Patent and Trademark Office duly and legally issued the '668 Patent to one of Arbutus's predecessor companies on September 2, 2014. The '668 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

ANSWER: Moderna admits that on September 2, 2014, the United States Patent and Trademark Office issued the '668 Patent, which states on its face that its title is "Lipid Formulations for Nucleic Acid Delivery," but denies that the patent claims patentable work. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 112 and therefore denies them.

113. Arbutus owns, and at all relevant times has owned, the '668 Patent.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 113 and therefore denies them.

114. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '668 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 114 and therefore denies them.

115. Claims of the '668 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof and methods of using them.

ANSWER: Insofar as Paragraph 115 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 115 and therefore denies them.

116. Moderna has directly infringed and continues to directly infringe claims of the '668 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '668 Patent, without authority or license to do so, during the term of the '668 Patent.

ANSWER: Insofar as Paragraph 116 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 116.

117. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '668 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '668 Patent.

ANSWER: Insofar as Paragraph 117 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 117.

118. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the '668 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '668 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 118 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 118.

119. Moderna has also infringed and continues to infringe the '668 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '668 patent if such combination occurred within the United States..

ANSWER: Insofar as Paragraph 119 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 119.

120. Moderna has also infringed and continues to infringe the '668 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 120 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 120.

121. For example, Claim 1 of the '668 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising up to 49.5 mol % of the total lipid present in the particle and comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

ANSWER: Moderna admits that Claim 1 of the '668 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising up to 49.5 mol % of the total lipid present in the particle and comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.". Moderna denies the remaining allegations in Paragraph 121.

122. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

ANSWER: Insofar as Paragraph 122 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 122.

123. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a non-cationic lipid comprising a mixture of a phospholipid and cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

ANSWER: Insofar as Paragraph 123 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 123.

124. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

ANSWER: Insofar as Paragraph 124 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 124.

125. When used as intended, the Accused Product infringes the '668 Patent's method claims.

ANSWER: Insofar as Paragraph 125 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 125.

126. For example, Claim 20 of the '668 Patent recites "[a] method for treating a disease or disorder in a mammalian subject in need thereof, the method comprising: administering to the mammalian subject a therapeutically effective amount of a nucleic acid-lipid particle of claim 1."

ANSWER: Moderna admits that Claim 20 of the '668 Patent recites "[a] method for treating a disease or disorder in a mammalian subject in need thereof, the method comprising: administering to the mammalian subject a therapeutically effective amount of a nucleic acid-lipid particle of claim 1." Moderna denies the remaining allegations in Paragraph 126.

127. Moderna's COVID-19 vaccine is intended for use in a method for treating a disease or disorder in a mammalian subject in need thereof, namely vaccination of a human against COVID-19. Moderna's COVID-19 vaccine comprises the nucleic acid-lipid particles of Claim 1 and it is intended for administration to a human in need thereof. Moderna's COVID-19 vaccine comprises a therapeutically effective amount of a nucleic acid-lipid particle of Claim 1. When used as intended, and as Moderna specifically instructs and encourages that it be used, the Accused Product infringes Claim 20.

ANSWER: Insofar as Paragraph 127 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Moderna's COVID-19 vaccine is intended to be used for vaccination of humans against COVID-19. Moderna denies the remaining allegations in Paragraph 127.

128. Moderna has known of the '668 Patent since before it commenced the infringing conductor has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's Patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents through *inter partes* review; and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. The '668 Patent is in the same family as, and is cited on the face of, the '435 Patent that Moderna challenged in *inter partes* review. Despite such knowledge, Moderna nonetheless has engaged in the manufacture,

offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

ANSWER: Insofar as Paragraph 128 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Protiva licensed certain patents for LNP technology to Acuitas, and that in 2015 and 2016, Acuitas sublicensed certain Protiva/Arbutus LNP patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, RSV, and Zika virus. Moderna further admits that it filed *inter partes* review petitions challenging three Arbutus patents before the United States Patent and Trademark Office. Moderna further admits that the '668 Patent is in the same family as, and is cited on the face of, the '435 Patent that Moderna challenged in *inter partes* review. Moderna denies the remaining allegations in Paragraph 128.

129. Moderna actively and knowingly has infringed the '668 Patent and actively and knowingly has induced infringement of the '668 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States, with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to infringe by administering the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

ANSWER: Insofar as Paragraph 129 contains legal conclusions, no response is required. Moderna denies the remaining allegations in Paragraph 129.

130. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '668 Patent, knowing the same to be especially made or

especially adapted for use in the infringement of the '668 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '668 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '668 Patent by administering the Accused Product in the United States.

ANSWER: Insofar as Paragraph 130 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 130.

131. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '668 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

ANSWER: Insofar as Paragraph 131 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 131.

132. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

ANSWER: Insofar as Paragraph 132 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 132.

133. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '668 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '668 Patent.

ANSWER: Insofar as Paragraph 133 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 133.

134. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '668 Patent.

ANSWER: Insofar as Paragraph 134 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 134.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 9,364,435

135. Paragraphs 1 through 124 are incorporated by reference as if fully set forth herein.

ANSWER: Moderna repeats and incorporates by references it responses to paragraphs 1-134 of the Amended Complaint.

136. The United States Patent and Trademark Office duly and legally issued the '435 Patent to one of Arbutus's predecessor companies on June 14, 2016. The '435 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

ANSWER: Moderna admits that on June 14, 2016, the United States Patent and Trademark Office issued the '435 Patent, which states on its face that its title is "Lipid Formulations for Nucleic Acid Delivery," but denies that the patent claims patentable work. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 136 and therefore denies them.

137. Arbutus owns, and at all relevant times has owned, the '435 Patent.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 137 and therefore denies them.

138. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '435 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 138 and therefore denies them.

139. Claims of the '435 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof and methods of using them.

ANSWER: Insofar as Paragraph 139 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 139 and therefore denies them.

140. Moderna has directly infringed and continues to directly infringe claims of the '435 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using **within** the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '435 Patent, without authority or license to do so, during the term of the '435 Patent.

ANSWER: Insofar as Paragraph 140 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 140.

141. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '435 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '435 Patent.

ANSWER: Insofar as Paragraph 141 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 141.

142. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the '435 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '435 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '435 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 142 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 142.

143. Moderna has also infringed and continues to infringe the '435 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '435 patent if such combination occurred within the United States.

ANSWER: Insofar as Paragraph 143 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 143.

144. Moderna has also infringed and continues to infringe the '435 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially

adapted for use in the infringement of the '435 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 144 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 144.

145. The Accused Product infringes at least Claim 7 of the '435 Patent.

ANSWER: Insofar as Paragraph 145 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 145.

146. Claim 7 of the '435 Patent depends from Claims 1 and 5. Claim 1 of the '435 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle; (c) non-cationic lipid comprising from 13 mol % to 49.5 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle." Claim 5 further requires "[t]he nucleic acid-lipid particle of claim 1, wherein the non-cationic lipid comprises a mixture of a phospholipid and cholesterol or a derivative thereof." Claim 7 further requires "[t]he nucleic acid-lipid particle of claim 5, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle."

ANSWER: Moderna admits that Claim 7 of the '435 Patent depends from Claims 1 and 5. Moderna admits that Claim 1 of the '435 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle; (c) non-cationic lipid comprising from 13 mol % to 49.5 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle." Moderna admits that Claim 5 of the '435 Patent recites "[t]he nucleic acid-lipid particle of claim 1, wherein the non-cationic lipid comprises a mixture of a phospholipid and cholesterol or a derivative thereof." Moderna admits that Claim 7 of the '435 Patent recites "[t]he nucleic acid-lipid particle of claim 5, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle." Moderna denies the remaining allegations in Paragraph 146.

147. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

ANSWER: Insofar as Paragraph 147 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 147.

148. The Accused Product comprises an ionizable cationic lipid (SM-102), a non-cationic lipid (a mixture of phospholipid and cholesterol), and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid conjugate).

ANSWER: Insofar as Paragraph 148 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 148.

149. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles comprising the following lipids in the following ratio of the total lipid present in the particle: 50 mol % of an ionizable cationic lipid; 48.5 mol % of a non-cationic lipid; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

ANSWER: Insofar as Paragraph 149 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 149.

150. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles where the non-cationic lipid comprises a mixture of a phospholipid and cholesterol. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises nucleic acid-lipid particles where 10 mol % of the total lipid present in the particle is a phospholipid.

ANSWER: Insofar as Paragraph 150 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 150.

151. When used as intended, the Accused Product infringes the ’435 Patent’s method claims.

ANSWER: Insofar as Paragraph 151 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 151.

152. For example, Claim 17 of the ’435 Patent recites a “method for treating a disease or disorder in a mammalian subject in need thereof, the method comprising: administering to the mammalian subject a therapeutically effective amount of a nucleic acid-lipid particle of claim 1.”

ANSWER: Moderna admits that Claim 17 of the '435 Patent recites a "method for treating a disease or disorder in a mammalian subject in need thereof, the method comprising: administering to the mammalian subject a therapeutically effective amount of a nucleic acid-lipid particle of claim 1." Moderna denies the remaining allegations in Paragraph 152.

153. The Accused Product is intended for use in a method for treating a disease or disorder in a mammalian subject in need thereof, namely vaccination of a human against COVID-19. The Accused Product comprises the nucleic acid-lipid particles of Claim 1 and it is intended for administration to a human in need thereof. The Accused Product comprises a therapeutically effective amount of a nucleic acid-lipid particle of Claim 1. When used as intended, and as Moderna specifically instructs and encourages that it be used, the Accused Product infringes Claim 17.

ANSWER: Insofar as Paragraph 153 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Moderna's COVID-19 vaccine is intended to be used for vaccination of humans against COVID-19. Moderna denies the remaining allegations in Paragraph 153.

154. Moderna has known of the '435 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's Patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents, including the '435 Patent, through *inter partes* review, and Moderna has repeatedly made public statements regarding Arbutus's LNP technology and patents. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

ANSWER: Insofar as Paragraph 154 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Protiva licensed certain patents for LNP technology to Acuitas, and that in 2015 and 2016, Acuitas sublicensed certain Protiva/Arbutus LNP patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, RSV, and Zika virus. Moderna further admits that it filed *inter partes*

review petitions challenging three Arbutus patents, including the '435 Patent, before the United States Patent and Trademark Office. Moderna denies the remaining allegations in Paragraph 154.

155. Modern actively and knowingly has infringed the '435 Patent and actively and knowingly induced infringement of the '435 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '435 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to infringe by administering the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

ANSWER: Insofar as Paragraph 155 contains legal conclusions, no response is required. Moderna denies the remaining allegations in Paragraph 155.

156. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '435 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '435 Patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '435 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '435 Patent by administering the Accused Product in the United States.

ANSWER: Insofar as Paragraph 156 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 156.

157. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '435 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

ANSWER: Insofar as Paragraph 157 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 157.

158. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

ANSWER: Insofar as Paragraph 158 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 158.

159. Moderna has undertaken its infringing actions despite knowing that such actions infringed one or more claims of the '435 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '435 Patent.

ANSWER: Insofar as Paragraph 159 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 159.

160. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '435 Patent.

ANSWER: Insofar as Paragraph 160 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 160.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 9,504,651

161. Paragraphs 1 through 148 are incorporated by reference as if fully set forth herein.

ANSWER: Moderna repeats and incorporates by references it responses to paragraphs 1-160 of the Amended Complaint.

162. The United States Patent and Trademark Office duly and legally issued the '651 Patent to one of Arbutus's predecessor companies on November 29, 2016. The '651 Patent is titled "Lipid Compositions for Nucleic Acid Delivery."

ANSWER: Moderna admits that on November 29, 2016, the United States Patent and Trademark Office issued the '651 Patent, which states on its face that its title is "Lipid Compositions for Nucleic Acid Delivery," but denies that the patent claims patentable work. Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 162 and therefore denies them.

163. Arbutus owns, and at all relevant times has owned, the '651 Patent.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 163 and therefore denies them.

164. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '651 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 164 and therefore denies them.

165. Claims of the '651 Patent cover, among other things, lipid vesicle formulations comprising mRNA.

ANSWER: Insofar as Paragraph 165 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 165 and therefore denies them.

166. Moderna has directly infringed and continues to directly infringe the claims of the '651 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product, incorporating Arbutus's patented LNP delivery technology covered by the '651 Patent, without authority or license to do so, during the term of the '651 Patent.

ANSWER: Insofar as Paragraph 166 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 166.

167. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '651 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '651 Patent.

ANSWER: Insofar as Paragraph 167 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 167.

168. Moderna has contributed, and continues to contribute, to the infringement of one or more claims of the '651 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented

manufacture, combination or composition, constituting a material part of the invention of the '651 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 168 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 168.

169. Moderna has also infringed and continues to infringe the '651 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '651 patent if such combination occurred within the United States.

ANSWER: Insofar as Paragraph 169 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 169.

170. Moderna has also infringed and continues to infringe the '069 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 170 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 170.

171. For example, Claim 1 of the '651 Patent recites a "lipid vesicle formulation comprising: (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid; and (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles." Claim 9 of the '651 Patent further requires "[t]he lipid vesicle formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle."

ANSWER: Moderna admits that Claim 1 of the '651 Patent recites a "lipid vesicle formulation comprising: (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid; and (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles." Moderna further admits that Claim 9 of the '651 Patent recites "[t]he lipid vesicle

formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle." Moderna denies the remaining allegations in Paragraph 171.

172. The Accused Product is a lipid vesicle formulation comprising mRNA and lipid vesicles. The mRNA in the Accused Product encodes the COVID-19 spike protein.

ANSWER: Insofar as Paragraph 172 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 172.

173. The Accused Product comprises a lipid vesicle comprising the following lipids: an ionizable cationic lipid (SM-102); an amphipathic lipid (DSPC); and a PEG-lipid.

ANSWER: Insofar as Paragraph 173 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 173.

174. Upon information and belief, in connection with the Accused Product, Moderna makes a lipid vesicle formulation wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.

ANSWER: Insofar as Paragraph 174 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 174.

175. On information and belief, Moderna has known of the '651 Patent since before it commenced the infringing conduct or has been willfully blind to its existence and contents since then. Moderna has long been aware of and actively monitored Arbutus's Patent estate. Moderna secured unauthorized limited sublicenses to Arbutus's LNP-related patents through Acuitas; Moderna later sought to invalidate three of Arbutus's LNP-related patents through *inter partes* review, and Moderna bas repeatedly made public statements regarding Arbutus's LNP technology and patents. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

ANSWER: Insofar as Paragraph 175 contains legal conclusions, no response is required. To the extent a response is required, Moderna admits that Protiva licensed certain patents for LNP technology to Acuitas, and that in 2015 and 2016, Acuitas sublicensed certain Protiva/Arbutus LNP patents to Moderna for certain products against four viral targets: Influenza A, Chikungunya virus, RSV, and Zika virus. Moderna further admits that it filed *inter partes*

review petitions challenging three Arbutus patents before the United States Patent and Trademark Office. Moderna denies the remaining allegations in Paragraph 175.

176. Moderna actively and knowingly has infringed the '651 Patent and actively and knowingly induced infringement of the '651 Patent by others. After Moderna knew or should have known that the Accused Product infringed, it applied for and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it contracted with multiple companies to manufacture the Accused Product, both in the United States and abroad, with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to administer the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

ANSWER: Insofar as Paragraph 176 contains legal conclusions, no response is required. Moderna denies the remaining allegations in Paragraph 176.

177. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '651 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '651 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it pursued and obtained EUA and then full approval from the FDA to market and sell the Accused Product in the United States with the specific intent to induce customers to purchase the Accused Product and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '651 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '651 Patent by administering the Accused Product in the United States.

ANSWER: Insofar as Paragraph 177 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 177.

178. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '651 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of Moderna's COVID-19 vaccine into the United States, and/or by actively inducing others to do the same, and/or by contributing to the

same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

ANSWER: Insofar as Paragraph 178 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 178.

179. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

ANSWER: Insofar as Paragraph 179 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 179.

180. Moderna has undertaken their infringing actions despite knowing that such actions infringed one or more claims of the '651 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '651 Patent.

ANSWER: Insofar as Paragraph 180 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 180.

181. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '651 Patent.

ANSWER: Insofar as Paragraph 181 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 181.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 11,141,378

182. Paragraphs 1 through 181 are incorporated by reference as if fully set forth herein.

ANSWER: Moderna repeats and incorporates by references it responses to paragraphs 1-181 of the Amended Complaint.

183. The United States Patent and Trademark Office duly and legally issued the '378 Patent to Arbutus on October 12, 2021. The '378 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

ANSWER: Moderna admits that on October 12, 2021, the United States Patent and Trademark Office issued the '378 Patent, which on its face states that its title is "Lipid Formulations for Nucleic Acid Delivery," but denies that the patent claims patentable work.

Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 183 and therefore denies them.

184. Arbutus owns, and at all relevant times has owned, the '378 Patent.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 184 and therefore denies them.

185. Genevant holds, and at all relevant times has held, a license to Exclusive Rights in the '378 Patent for certain fields of use, which include the Accused Product. Genevant has the right to sue and seek damages for the infringement alleged herein.

ANSWER: Moderna lacks knowledge and information sufficient to form a belief about the truth of the allegations in Paragraph 185 and therefore denies them.

186. Claims of the '378 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

ANSWER: Insofar as Paragraph 186 contains legal conclusions, no response is required. To the extent a response is required, Moderna lacks knowledge and information sufficient to form a belief about the truth of the remaining allegations in Paragraph 186 and therefore denies them.

187. Moderna has directly infringed- and continues to directly infringe claims of the '378 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, or using within the United States, or importing into the United States, the Accused Product incorporating Arbutus's patented LNP delivery technology covered by the '378 Patent, without authority or license to do so, during the term of the '378 Patent.

ANSWER: Insofar as Paragraph 187 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 187.

188. Moderna actively, knowingly, and intentionally has induced, and continues to induce, infringement of one or more claims of the '378 Patent under 35 U.S.C. § 271(b) by actively encouraging others to make and use the Accused Product in the United States in a manner specifically intended to infringe the '378 Patent.

ANSWER: Insofar as Paragraph 188 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 188.

189. Moderna has and continues to contribute to the infringement of one or more claims of the '378 Patent by others under 35 U.S.C. § 271(c) by offering to sell and selling within the United States, or importing into the United States, a component of a patented manufacture, combination or composition, constituting a material part of the invention of the '378 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 189 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 189.

190. Moderna has also infringed and continues to infringe the '378 Patent under 35 U.S.C. § 271(f)(1) by intentionally supplying or causing to be supplied in or from the United States all or a substantial portion of the components of the Accused Product—including mRNA and [redacted]—where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the '378 patent if such combination occurred within the United States.

ANSWER: Insofar as Paragraph 190 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 190.

191. Moderna has also infringed and continues to infringe the '378 Patent under 35 U.S.C. § 271(f)(2) by intentionally supplying or causing to be supplied in or from the United States a component of the Accused Product—such as mRNA or [redacted]—where such components are uncombined in whole or in part, knowing such component is especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Insofar as Paragraph 191 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 191.

192. For example, Claim 1 of the '378 Patent recites a "nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle." An ionizable lipid having a protonatable tertiary amine becomes a cationic lipid.

ANSWER: Moderna admits that Claim 1 of the '378 Patent recites a "nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total

lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle." Moderna further admits that an ionizable lipid having a protonatable tertiary amine becomes a cationic lipid. Moderna denies the remaining allegations in Paragraph 192.

193. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

ANSWER: Insofar as Paragraph 193 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 193.

194. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: an ionizable cationic lipid (SM-102); a non-cationic lipid comprising a mixture of a phospholipid and cholesterol; and a conjugated lipid that inhibits aggregation of particles (a PEG-lipid).

ANSWER: Insofar as Paragraph 194 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 194.

195. On information and belief, as indicated in the Moderna/NIH preprint and in International Patent Publication WO 2021/159130, the Accused Product comprises a cationic lipid having a protonatable tertiary amine; 10 mol % of a phospholipid; 38.5 mol % of cholesterol; and 1.5 mol % of a conjugated lipid that inhibits aggregation of particles.

ANSWER: Insofar as Paragraph 195 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 195.

196. The '378 Patent issued on October 12, 2021. That day, Genevant sent Moderna an email notice that Moderna may be infringing one or more claims of the '378 Patent.

ANSWER: Moderna admits the allegations in Paragraph 196.

197. Despite such knowledge, Moderna nonetheless has engaged in the manufacture, offer for sale, sale or use of the Accused Product within the United States, the importation of the Accused Product into the United States, and/or the supply or causing to be supplied from the United States of a component or all or a substantial portion of components of the Accused Product, in violation of Plaintiffs' patent rights.

ANSWER: Insofar as Paragraph 197 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 197.

198. Moderna actively and knowingly has infringed the '378 Patent and actively and knowingly induced infringement of the '378 Patent by others. After Moderna knew or should have known that the Accused Product infringed, Moderna continued to seek and has now received full FDA approval for its Accused Product, with the specific intent to induce customers to purchase them and for people to have the Accused Product administered to them within the United States. At all times after Moderna knew or should have known that the Accused Product infringed, it has maintained active contracts with multiple companies to manufacture the Accused Product, both in the United States and abroad, and supplied those companies, or caused those companies to be supplied, from the United States with components especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, all with the specific intent to induce those companies to make its infringing product. Upon information and belief, Moderna is continuing to seek and negotiate similar contracts with companies to manufacture the Accused Product. Upon information and belief, Moderna actively markets the Accused Product to governments and other entities with the intent for healthcare professionals to infringe by administering the Accused Product to millions and potentially billions of people as a means of protection against SARS-CoV-2 infection.

ANSWER: Insofar as Paragraph 198 contains legal conclusions, no response is required. Moderna denies the remaining allegations in Paragraph 198.

199. Moderna actively and knowingly contributes to the infringement of healthcare professionals in the United States who administer or otherwise use the Accused Product in the United States. After Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '378 Patent, knowing the same to be especially made or especially adapted for use in the infringement of the '378 Patent and not a staple article or commodity of commerce suitable for substantial non-infringing use, it continued to pursue and has now obtained full FDA approval to market and sell the Accused Product in the United States. At all times after Moderna knew or should have known that the Accused Product constituted a material part of the invention of the '378 Patent, it contracted with others to manufacture the Accused Product, both in the United States and abroad, knowing healthcare professionals would directly infringe one or more claims of the '378 Patent by administering the Accused Product in the United States.

ANSWER: Insofar as Paragraph 199 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 199.

200. Arbutus and Genevant are entitled to a judgment that Moderna infringes the claims of the '378 Patent by engaging in the manufacture, use, sale, or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same, and/or by contributing to the same, and/or by supplying a component or all or a substantial portion of components of the Accused Product.

ANSWER: Insofar as Paragraph 200 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 200.

201. Moderna's infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, of at least a reasonable royalty.

ANSWER: Insofar as Paragraph 201 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 201.

202. Moderna has undertaken its infringing actions despite knowing that such actions infringe one or more claims of the '378 Patent. As such, Moderna has and continues to willfully infringe one or more claims of the '378 Patent.

ANSWER: Insofar as Paragraph 202 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 202.

203. This is an exceptional case. Genevant and Arbutus are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Moderna's infringement of the '378 Patent.

ANSWER: Insofar as Paragraph 203 contains legal conclusions, no response is required. To the extent a response is required, Moderna denies the allegations in Paragraph 203.

PRAYER FOR RELIEF

The Amended Complaint recites a prayer for relief to which no response is required. To the extent a response is required, Moderna denies that Plaintiffs are entitled to any remedy or relief.

JURY DEMAND

Moderna joins Plaintiffs' request for a jury trial on all issues triable by jury.

GENERAL DENIAL

Moderna denies all allegations in Plaintiffs' Amended Complaint not expressly admitted.

DEFENSES

1. Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in the Amended Complaint, Defendants rely upon the following defenses, whether pled as an affirmative defense or otherwise:

FIRST DEFENSE (NON-INFRINGEMENT)

2. Moderna does not infringe, literally or under the doctrine of equivalents, and at all relevant time to this action has not infringed, any valid claim of the Asserted Patents.

SECOND DEFENSE (INVALIDITY)

3. The Asserted Patents are invalid for failure to satisfy one or more of the conditions and requirements of patentability set forth in 35 U.S.C. §§ 101 et seq., including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, or under any of the judicially created doctrines of invalidity.

THIRD DEFENSE (FAILURE TO STATE A CLAIM)

4. The Amended Complaint fails to state a claim upon which relief can be granted

FOURTH DEFENSE (NO WILLFUL INFRINGEMENT)

5. Moderna has not willfully infringed, and does not willfully infringe, any valid claim of any of the Asserted Patents.

FIFTH DEFENSE (NO EXCEPTIONAL CASE)

6. Moderna's actions in defending this case or otherwise does not give rise to an exceptional case in Plaintiffs' favor under 35 U.S.C. § 285.

SIXTH DEFENSE (PROSECUTION HISTORY DISCLAIMER AND ESTOPPEL)

7. Plaintiffs are barred, based on statements, representations, and admissions made during prosecution of the patent applications resulting in the Asserted Patents or related patent applications, from asserting any interpretation of any valid claims of the Asserted Patents that

would be broad enough to cover any accused product alleged to infringe the Asserted Patents, either literally or by application of the doctrine of equivalents, or under any theory of infringement.

SEVENTH DEFENSE (ESTOPPEL, WAIVER, ACQUIESCENCE, LACHES, AND UNCLEAN HANDS)

8. Plaintiffs' claims and/or requested relief are barred by one or more of the doctrines of estoppel, waiver, acquiescence, laches (including prosecution laches), and unclean hands from enforcing, or claiming a reasonably royalty and/or lost profits with respect to any claim of any of the Asserted Patents.

EIGHTH DEFENSE (35 U.S.C. § 271(E)(1))

9. Aspects of Moderna's alleged infringement of the Asserted Patents are reasonably related to Moderna's development and submission of information to the FDA for the Emergency Use Authorization and the Biologics License Application regarding the COVID-19 Vaccine.

10. Accordingly, such claims for infringement against Moderna are barred by the safe harbor of 35 U.S.C. § 271(e)(1).

NINTH DEFENSE (GOVERNMENT SALES)

11. Moderna's manufacture and sale of COVID-19 Vaccine pursuant to the C0100 Contract was and continues to be for the benefit of the U.S. Government and with the U.S. Government's authorization and consent under 28 U.S.C. § 1498(a).

12. Accordingly, Plaintiffs' claims based on Moderna's manufacture and sale of COVID-19 Vaccine pursuant to the C0100 Contract are barred by 28 U.S.C. § 1498(a).

TENTH DEFENSE (PROSECUTION LACHES)

13. Plaintiffs' claims are barred by the doctrine of prosecution laches due to their unreasonable and unexplained delay prosecuting claims asserted against Moderna.

14. Arbutus has caused unreasonable and inexcusable delay while prosecuting at least the ’651 and ’378 patents, all while watching the industry—including Moderna—develop and make mRNA vaccines, including Moderna’s Accused Products. Moderna suffered prejudice by reason of delay by Arbutus. Thus, at least the ’651 and ’378 patents are unenforceable under the doctrine of laches. *See Hyatt v. Hirshfeld*, 998 F.3d 1347, 1360 (Fed. Cir. 2021).

15. The ’651 patent purports to claim priority to Provisional Application No. 60/392,887, which was filed on June 28, 2002. Arbutus waited 12 years, until June 13, 2014, to file Application No. 14/304,578, which, after multiple amendments, issued as the ’651 patent. While all previously filed applications in the family relate to “liposomal apparatus and manufacturing methods,” *see, e.g.*, U.S. App. Nos. 13/684,066 and 12/965,555, the ’651 patent, instead, claims a “lipid vesicle formulation comprising” mRNA. Arbutus waited until the field of nucleic acid therapeutics and LNP delivery technology, including Moderna, began to develop mRNA-based therapeutics to file the application for the ’651 patent. This is evidenced not only by the unreasonable and inexcusable delay of 12 years, but also by the fact that none of the examples in the ’651 patent are directed to mRNA delivery, and the specification of the ’651 patent focuses on delivery of plasmid DNA, rather than mRNA. *See, e.g.*, ’651 patent at cols. 14–19 (Examples 1–8), at 2:17–19 (“The present invention can be used to form lipid vesicles that contain encapsulated plasmid DNA or small molecule drugs.”). Additionally, during prosecution of the ’651 patent family, Arbutus repeatedly delayed examination and thus allowance, which compounds the prejudice from its decision to delay seeking claims to mRNA until a decade after its purported priority date. *See*, *e.g.* ’651 File History, 8/18/2015 and 5/9/2016 Requests for Continued Examination. Arbutus’s designed delay of applying for the ’651 patent prejudices

Moderna, because Moderna had already invested in and begun developing mRNA-based therapeutics and mRNA delivery technology during the delay.

16. The '378 patent purports to claim priority to Provisional Application No. 61/045,228, which was filed on Apr. 15, 2008. Yet, Arbutus waited 13 years to file Application No. 17/227,802 that led to the '378 patent. Specifically, the application was filed in April 2021, shortly after Moderna's COVID-19 Vaccine was approved and rolled out. The application is also in a long line of continuation applications, including four applications that Arbutus filed and then abandoned, from the '069 patent, which was filed in 2009. Most of the abandoned applications share an identical set of initial claims, and received similar anticipation/obviousness rejections based on at least of one of the same prior art references. *See, e.g.*, 17/094,724 File History, Nov. 10, 2020 Claims, Nov. 17, 2022 Non-Final Rejection; 16/422,441 File History, May 24, 2019 Claims, May 11, 2020 Non-Final Rejection; 15/840,933 File History, Dec. 13, 2017 Claims, Jan. 18, 2018 Non-Final Rejection. For all the abandoned applications, Arbutus followed the script of first filing incomplete initial applications, which knowingly delayed the start of the examination, then filing for at least one extension of time in each of its abandoned applications, with each extension adding 2 to 5 months, causing further delay. *See, e.g.*, 17/094,724 File History, Apr. 12, 2021 and May 16, 2023 Extension of Time; 16/422,441 File History, Jan. 3, 2020 and Nov. 10, 2020 Extension of Time; 15/840,933 File History, Oct. 29, 2018 and May 14, 2019 Extension of Time; 15/670,742 File History, Dec. 14, 2017 Extension of Time. This chain of events establishes a clear pattern of Arbutus deliberately filing and abandoning rounds of similar applications to prolong the life of the family chain so it can sit and monitor the field of nucleic acid therapeutics and LNP delivery technology, including Moderna.

17. While all the previously filed patents in the family recite a "nucleic acid-lipid particle comprising" at least 50 mol % of a cationic lipid, Arbutus waited around a decade to file the application for the '378 patent to attempt to expand the scope of the claims in the family to recite a "nucleic acid-lipid particle comprising" less than 50 mol % of a cationic lipid. In the application that led to the '378 patent, Arbutus also appears to have amended the claims to remove the explicit lower limit of cationic lipids without drawing the examiner's attention to the omission as part of a prosecution strategy to obscure that Arbutus sought ratios of cationic lipid that were not supported by the specification and would, if not included, conflict with the bases for patentability that Arbutus submitted many years earlier, much farther back in the chain of priority. As a result of Arbutus's designed delay, the '378 patent only became public and issued only after Moderna had rolled out its COVID-19 Vaccine. Moderna is thus prejudiced by Arbutus's unreasonable and inexcusable delay because Moderna had already worked on, invested in, and used its proprietary LNP and COVID-19 Vaccine during the delay.

ADDITIONAL DEFENSES

18. Moderna reserves the right to assert any additional defenses or counterclaims that discovery may reveal.

PRAYER FOR RELIEF

WHEREFORE, for its Answer and Declaratory Judgment Counterclaims, Moderna requests the following judgments and relief against Plaintiffs:

(i) That all claims against Moderna be dismissed with prejudice and that all relief requested by Plaintiffs be denied;

(ii) That a judgment be entered declaring that Moderna has not infringed and does not infringe, either directly or indirectly, any valid claim of the Asserted Patents, either literally or under the doctrine of equivalents;

(iii) That a judgment be entered declaring that the claims of the Asserted Patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, and/or 112;

(iv) An award of Moderna's costs as the prevailing party;

(v) That a judgment be entered declaring that this case is exceptional under 35 U.S.C. § 285, and accordingly that Moderna is entitled to recover reasonable attorneys' fees and costs upon prevailing in this action; and

(vi) That Moderna be awarded such other relief that the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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May 15, 2024

CERTIFICATE OF SERVICE

I hereby certify that on May 15, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 15, 2024, upon the following in the manner indicated:

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